



## Clinical trial results:

**A multicenter, randomized, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of finerenone on morbidity and mortality in participants with heart failure (NYHA II-IV) and left ventricular ejection fraction 40% (LVEF 40%).**

### Summary

EudraCT number	2020-000306-29
Trial protocol	DE GB DK AT HU BG PT NL SK GR CZ LT FI LV IT RO
Global end of trial date	14 June 2024

### Results information

Result version number	v1 (current)
This version publication date	15 June 2025
First version publication date	15 June 2025

### Trial information

#### Trial identification

Sponsor protocol code	20103
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04435626
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser-Wilhelm-Allee, Leverkusen, Germany, D-51368
Public contact	Bayer Clinical Trials Contact, Bayer AG, 0049 30300139003, clinical-trials-contact@bayer.com
Scientific contact	Bayer Clinical Trials Contact, Bayer AG, 0049 30300139003, clinical-trials-contact@bayer.com

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	14 June 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	14 June 2024
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To demonstrate the superiority of finerenone to placebo in reducing the rate of the composite CV endpoint of CV death and total heart failure (HF) events in HF patients (LVEF  $\geq 40\%$ ).

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and the International Conference on Harmonization guideline E6: Good Clinical Practice (GCP). Before entering the study, the informed consent form was read by and explained to all subjects and/or their legally authorized representative. Participating subjects and/or their legally authorized representative signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 September 2020
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	Netherlands: 64
Country: Number of subjects enrolled	Poland: 259
Country: Number of subjects enrolled	Portugal: 88
Country: Number of subjects enrolled	Romania: 193
Country: Number of subjects enrolled	Slovakia: 262
Country: Number of subjects enrolled	Spain: 353
Country: Number of subjects enrolled	United Kingdom: 99
Country: Number of subjects enrolled	Austria: 73
Country: Number of subjects enrolled	Bulgaria: 275
Country: Number of subjects enrolled	Czechia: 206
Country: Number of subjects enrolled	Denmark: 79
Country: Number of subjects enrolled	Finland: 20
Country: Number of subjects enrolled	Germany: 20
Country: Number of subjects enrolled	Hungary: 267
Country: Number of subjects enrolled	Italy: 227
Country: Number of subjects enrolled	Latvia: 65
Country: Number of subjects enrolled	Lithuania: 100

Country: Number of subjects enrolled	Australia: 32
Country: Number of subjects enrolled	Israel: 181
Country: Number of subjects enrolled	New Zealand: 40
Country: Number of subjects enrolled	Russian Federation: 300
Country: Number of subjects enrolled	Ukraine: 327
Country: Number of subjects enrolled	China: 538
Country: Number of subjects enrolled	India: 28
Country: Number of subjects enrolled	Japan: 286
Country: Number of subjects enrolled	Korea, Republic of: 74
Country: Number of subjects enrolled	Malaysia: 57
Country: Number of subjects enrolled	Canada: 116
Country: Number of subjects enrolled	United States: 355
Country: Number of subjects enrolled	Argentina: 211
Country: Number of subjects enrolled	Brazil: 185
Country: Number of subjects enrolled	Colombia: 167
Country: Number of subjects enrolled	Mexico: 78
Country: Number of subjects enrolled	Greece: 217
Country: Number of subjects enrolled	Türkiye: 159
Worldwide total number of subjects	6001
EEA total number of subjects	2768

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1262
From 65 to 84 years	4271
85 years and over	468

## Subject disposition

### Recruitment

Recruitment details:

Study was conducted at multiple centers in 37 countries/regions between 14-Sep-2020 (first participant first visit) and 14-Jun-2024 (last participant last visit).

### Pre-assignment

Screening details:

Of the 7463 screened participants, 1447 were screening failures, 6016 were randomized. Of the 3011 participants randomized into the finerenone group and the 3005 into the placebo group, 8 and 7 participants respectively were prospectively excluded from analysis due to major GCP violations.

### Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Data analyst, Carer, Subject, Assessor

### Arms

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

Arm description:

Participants received finerenone 10 mg, 20 mg or 40 mg once daily.

Arm type	Experimental
Investigational medicinal product name	Finerenone
Investigational medicinal product code	BAY94-8862
Other name	Kerendia, Firalta, Lyvelsa
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Oral tablet; For participants with an eGFR  $\leq 60$  mL/min/1.73 m<sup>2</sup>: Starting dose is 10 mg once daily (OD) and maximum dose 20 mg OD. For participants with an eGFR  $> 60$  mL/min/1.73 m<sup>2</sup>: Starting dose is 20 mg OD and maximum dose 40 mg OD. Dose could be up-titrated from Month 1 onwards or down-titrated at any time during the study. Study medication was administered once daily in the morning, until the trial was completed provided there were no safety grounds for discontinuing treatment.

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

Participants received matching placebo once daily.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Matching placebo, oral tablet, until the trial was completed provided there were no safety grounds for discontinuing treatment

<b>Number of subjects in period 1</b>	Finerenone	Placebo
Started	3003	2998
Completed	2996	2986
Not completed	7	12
Consent withdrawn by subject	6	7
Lost to follow-up	1	5

## Baseline characteristics

### Reporting groups

Reporting group title	Finerenone
Reporting group description:	
Participants received finerenone 10 mg, 20 mg or 40 mg once daily.	
Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo once daily.	

Reporting group values	Finerenone	Placebo	Total
Number of subjects	3003	2998	6001
Age categorical			
Units: Subjects			
Adults (18-64 years)	643	619	1262
From 65-84 years	2134	2137	4271
85 years and over	226	242	468
Age continuous			
Units: years			
arithmetic mean	71.94	72.04	
standard deviation	± 9.60	± 9.69	-
Gender categorical			
Units: Subjects			
Female	1355	1377	2732
Male	1648	1621	3269
NYHA class			
The New York Heart Association (NYHA) Functional Classification is a simple scale that classifies patients with heart failure based on the severity of their symptoms and how those symptoms affect their physical activity, which ranges from Class I to Class IV, a lower class number is indicative of a better condition.			
Units: Subjects			
NYHA class II	2081	2065	4146
NYHA class III	903	910	1813
NYHA class IV	18	23	41
missing	1	0	1
Baseline LVEF			
LVEF: Left ventricular ejection fraction, which is used to assess how well the left ventricle of the heart pumps blood with each beat. A normal LVEF ranges from 55% to 70%. When the LVEF is below 55%, it suggests that the heart's pumping ability is reduced.			
Units: percent			
arithmetic mean	52.64	52.49	
standard deviation	± 7.82	± 7.81	-

## End points

### End points reporting groups

Reporting group title	Finerenone
Reporting group description:	
Participants received finerenone 10 mg, 20 mg or 40 mg once daily.	
Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo once daily.	

### Primary: Occurrence of the composite endpoint of cardiovascular death and total (first and recurrent) heart failure events

End point title	Occurrence of the composite endpoint of cardiovascular death and total (first and recurrent) heart failure events
End point description:	
Number of composite endpoint events of cardiovascular death and total (first and recurrent) heart failure (HF) events (hospitalization for heart failure or urgent HF visit) in HF patients.	
End point type	Primary
End point timeframe:	
From randomization up until the end of study, with an average study duration of 32 months	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3003	2998		
Units: events	1083	1283		

### Statistical analyses

Statistical analysis title	Rate Ratio
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	6001
Analysis specification	Pre-specified
Analysis type	superiority <sup>[1]</sup>
P-value	= 0.0072 <sup>[2]</sup>
Method	stratified Andersen-Gill model
Parameter estimate	Rate ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.95

Notes:

[1] - Stratified Andersen-Gill model with robust sandwich estimate for the covariance matrix of recurrent events

[2] - Two-sided p-value; p-value threshold=0.04967

### **Primary: Occurrence of the Composite Endpoint of Cardiovascular Death and Total (First and Recurrent) Heart Failure Events**

End point title	Occurrence of the Composite Endpoint of Cardiovascular Death and Total (First and Recurrent) Heart Failure Events <sup>[3]</sup>
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End point description:

Number of participants with composite endpoint events of cardiovascular death and total (first and recurrent) heart failure (HF) events (hospitalization for heart failure or urgent HF visit) in HF patients.

End point type	Primary
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End point timeframe:

From randomization up until the end of study, with an average study duration of 32 months

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This primary endpoint shares identical statistical analysis with the previous one.

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3003	2998		
Units: participants	624	719		

### **Statistical analyses**

No statistical analyses for this end point

### **Secondary: Occurrence of total (first and recurrent) heart failure events**

End point title	Occurrence of total (first and recurrent) heart failure events
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End point description:

Number of total (first and recurrent) heart failure events.

End point type	Secondary
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End point timeframe:

From randomization up until the end of study, with an average study duration of 32 months

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3003	2998		
Units: events	842	1024		

### **Statistical analyses**



<b>Statistical analysis title</b>	Rate Ratio
Comparison groups	Placebo v Finerenone
Number of subjects included in analysis	6001
Analysis specification	Pre-specified
Analysis type	superiority <sup>[4]</sup>
P-value	= 0.0062 <sup>[5]</sup>
Method	Stratified Andersen-Gill model
Parameter estimate	Rate ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.94

Notes:

[4] - Stratified Andersen-Gill model with robust sandwich estimate for the covariance matrix of recurrent events

[5] - Two-sided p-value; p-value threshold=0.04967

### Secondary: Occurrence of total (first and recurrent) heart failure events

End point title	Occurrence of total (first and recurrent) heart failure events
End point description:	
Number of participants with total (first and recurrent) heart failure events.	
End point type	Secondary
End point timeframe:	
From randomization up until the end of study, with an average study duration of 32 months	

<b>End point values</b>	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3003	2998		
Units: participants	479	573		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from baseline in Total Symptom Score (TSS) of the Kansas City Cardiomyopathy Questionnaire (KCCQ)

End point title	Change from baseline in Total Symptom Score (TSS) of the Kansas City Cardiomyopathy Questionnaire (KCCQ)
End point description:	
The Kansas City Cardiomyopathy Questionnaire Total Symptom Score (KCCQ-TSS) is ranged from 0 to 100. A higher score (closer to 100) reflects fewer symptoms, indicating better heart failure symptom status.	
End point type	Secondary
End point timeframe:	
From baseline to Month 6, 9 and 12	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2731	2710		
Units: score on scale				
least squares mean (confidence interval 95%)	7.99 (7.37 to 8.62)	6.43 (5.79 to 7.07)		

## Statistical analyses

Statistical analysis title	Difference in LS Mean
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	5441
Analysis specification	Pre-specified
Analysis type	other <sup>[6]</sup>
P-value	< 0.0001 <sup>[7]</sup>
Method	Mixed Models Analysis
Parameter estimate	Difference in LS Mean
Point estimate	1.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	2.34

Notes:

[6] - mixed-effects model for repeated measures (MMRM)

[7] - Two-sided p-value

## Secondary: Improvement in NYHA class from baseline to Month 12

End point title	Improvement in NYHA class from baseline to Month 12
End point description:	The New York Heart Association (NYHA) Functional Classification is a simple scale that classifies patients with heart failure based on the severity of their symptoms and how those symptoms affect their physical activity, which ranges from Class I to Class IV, a lower class number is indicative of a better condition.
End point type	Secondary
End point timeframe:	
from baseline to Month 12	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3003	2998		
Units: Estimated proportion				
number (confidence interval 95%)	0.179 (0.163 to 0.195)	0.178 (0.162 to 0.194)		

## Statistical analyses

<b>Statistical analysis title</b>	Odds ratio Finerenone / Placebo
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	6001
Analysis specification	Pre-specified
Analysis type	other <sup>[8]</sup>
P-value	= 0.9295 <sup>[9]</sup>
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.15

Notes:

[8] - Logistic regression analysis

[9] - Two-sided p-value

## Secondary: First occurrence of renal composite events

End point title	First occurrence of renal composite events
End point description:	
Number of participants with renal composite events encompassing the components sustained decrease in eGFR $\geq 50\%$ relative to baseline over at least 4 weeks, sustained eGFR decline to $<15$ mL/min/1.73 m <sup>2</sup> over at least 4 weeks, initiation of chronic dialysis and renal transplantation.	
End point type	Secondary
End point timeframe:	
From randomization up to end of study visit, with an average study duration of 32 months	

<b>End point values</b>	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3003	2998		
Units: participants	75	55		

## Statistical analyses

<b>Statistical analysis title</b>	Cause-specific Hazard Ratio
Comparison groups	Finerenone v Placebo

Number of subjects included in analysis	6001
Analysis specification	Pre-specified
Analysis type	other <sup>[10]</sup>
P-value	= 0.1071 <sup>[11]</sup>
Method	Stratified log-rank test
Parameter estimate	Cause-specific Hazard Ratio
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.89

Notes:

[10] - Stratified Cox proportion hazards model

[11] - two-sided p-value

### Secondary: Occurrence of all-cause mortality (Full Analysis Set)

End point title	Occurrence of all-cause mortality (Full Analysis Set)
End point description:	
Number of participants with death due to any cause were reported as descriptive result. Number of participants with outcome death reported here includes deaths occurred after randomization until the end of the study visit. Deaths after end of study visit are not included in this table.	
End point type	Secondary
End point timeframe:	
From randomization until end of study, with an average of 32 months	

End point values	Finerenone	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3003	2998		
Units: participants	491	522		

### Statistical analyses

Statistical analysis title	Hazard Ratio
Comparison groups	Finerenone v Placebo
Number of subjects included in analysis	6001
Analysis specification	Pre-specified
Analysis type	other <sup>[12]</sup>
P-value	= 0.2794 <sup>[13]</sup>
Method	Stratified log-rank
Parameter estimate	Cause-specific hazard ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.06

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Notes:

[12] - Stratified Cox proportion hazards model

[13] - Two-sided p-value

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From start of the first study intervention up to 3 days after the last study intervention administration, with an average treatment duration of 28 months.

Adverse event reporting additional description:

Adverse events are reported for the safety analysis set (SAF) that comprised all randomized participants who took at least 1 dose of study drug (except those with critical GCP violations). Number of deaths (all causes) are reported for the SAF and include all deaths after randomization.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.0
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### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants randomized to this group received matching placebo once daily.

Reporting group title	Finerenone
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Reporting group description:

Participants with an eGFR  $\leq 60$  mL/min/1.73 m<sup>2</sup>: Starting dose is 10 mg once daily (OD) and maximum dose 20 mg OD. For participants with an eGFR  $> 60$  mL/min/1.73 m<sup>2</sup>: Starting dose is 20 mg OD and maximum dose 40 mg OD.

Serious adverse events	Placebo	Finerenone	
Total subjects affected by serious adverse events			
subjects affected / exposed	1213 / 2993 (40.53%)	1157 / 2993 (38.66%)	
number of deaths (all causes)	528	494	
number of deaths resulting from adverse events	239	204	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	3 / 2993 (0.10%)	2 / 2993 (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	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	4 / 2993 (0.13%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoma benign			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell small lymphocytic lymphoma			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	3 / 2993 (0.10%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of adrenal gland			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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 skin			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct cancer			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder neoplasm			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	6 / 2993 (0.20%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Breast cancer recurrent			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage II			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast neoplasm			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Carcinoma in situ of penis			



subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	6 / 2993 (0.20%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	3 / 2993 (0.10%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Gastrointestinal carcinoma			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hodgkin's disease			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lipoma			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone neoplasm			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer recurrent			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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 I			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	4 / 2993 (0.13%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma uterus			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant melanoma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinum neoplasm			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mesothelioma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to bone			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to lymph nodes			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spine			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neoplasm			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neoplasm skin			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal adenocarcinoma			

subjects affected / exposed	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Ovarian cancer			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Papillary serous endometrial carcinoma			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Prostate cancer metastatic			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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 the oral cavity			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous cell carcinoma of the tongue			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tonsil cancer			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric cancer			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour ulceration			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to salivary gland			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colon cancer metastatic			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Retroperitoneal neoplasm			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	10 / 2993 (0.33%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 12	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 6	
Metastases to central nervous system			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastric adenoma			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	9 / 2993 (0.30%)	11 / 2993 (0.37%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant mediastinal neoplasm			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraganglion neoplasm			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine tumour of the lung			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adrenal neoplasm			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic neoplasm			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip neoplasm			



subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration malignant			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rosai-Dorfman syndrome			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer recurrent			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Laryngeal cancer metastatic			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian granulosa cell tumour			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal squamous cell carcinoma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal papillary-mucinous carcinoma of pancreas			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myeloproliferative neoplasm			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal squamous cell carcinoma			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicular lymphoma stage II			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant gastric ulcer			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenoma			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	2 / 2993 (0.07%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic dissection			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Aortic stenosis			
subjects affected / exposed	7 / 2993 (0.23%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial thrombosis			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure fluctuation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism arterial			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery aneurysm			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	11 / 2993 (0.37%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			

subjects affected / exposed	7 / 2993 (0.23%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial haemorrhage			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	4 / 2993 (0.13%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Labile hypertension			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	1 / 2993 (0.03%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			

subjects affected / exposed	7 / 2993 (0.23%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	2 / 7	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoedema			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	9 / 2993 (0.30%)	12 / 2993 (0.40%)	
occurrences causally related to treatment / all	1 / 9	8 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachiocephalic artery stenosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic vascular disorder			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	8 / 2993 (0.27%)	10 / 2993 (0.33%)	
occurrences causally related to treatment / all	0 / 12	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachiocephalic arteriosclerosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive shock			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (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 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subgaleal haematoma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection rupture			



subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic arteriosclerosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Angioplasty			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve replacement			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toe amputation			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal laminectomy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal stone removal			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic floor repair			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leg amputation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia repair			
subjects affected / exposed	0 / 2993 (0.00%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			
subjects affected / exposed	2 / 2993 (0.07%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glossectomy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cryotherapy			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid endarterectomy			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardioversion			
subjects affected / exposed	3 / 2993 (0.10%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker removal			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker insertion			
subjects affected / exposed	4 / 2993 (0.13%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder calculus removal			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicectomy			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia repair			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrectomy			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatectomy			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colectomy			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac operation			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma evacuation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ablation			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac resynchronisation therapy			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve decompression			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery angioplasty			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery angioplasty			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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	1 / 2993 (0.03%)	1 / 2993 (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	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithotomy			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary arterial stent insertion			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip surgery			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary angioplasty			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder arthroplasty			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee operation			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator insertion			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker replacement			
subjects affected / exposed	4 / 2993 (0.13%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethrotomy			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal operation			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric calculus removal			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (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 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Percutaneous coronary intervention			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular lens implant			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eventration repair			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence surgery			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transcatheter aortic valve implantation			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic surgery			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial appendage closure			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug titration			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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			
Malaise			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			

subjects affected / exposed	4 / 2993 (0.13%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 4	1 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chest discomfort			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	22 / 2993 (0.74%)	23 / 2993 (0.77%)	
occurrences causally related to treatment / all	0 / 23	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Condition aggravated			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	52 / 2993 (1.74%)	29 / 2993 (0.97%)	
occurrences causally related to treatment / all	0 / 52	0 / 29	
deaths causally related to treatment / all	0 / 52	0 / 29	
Fatigue			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperpyrexia			



subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Impaired healing			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated hernia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	8 / 2993 (0.27%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	17 / 2993 (0.57%)	16 / 2993 (0.53%)	
occurrences causally related to treatment / all	0 / 17	0 / 16	
deaths causally related to treatment / all	0 / 17	0 / 16	
Sudden cardiac death			
subjects affected / exposed	16 / 2993 (0.53%)	14 / 2993 (0.47%)	
occurrences causally related to treatment / all	0 / 16	0 / 14	
deaths causally related to treatment / all	0 / 16	0 / 14	
General physical health deterioration			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pacemaker generated arrhythmia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic cardiac valve thrombosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental death			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Medical device site haematoma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	5 / 2993 (0.17%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyloidosis			
subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary amyloidosis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sarcoidosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactoid reaction			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Immobile			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast			

disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	3 / 2993 (0.10%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermenstrual bleeding			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal swelling			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (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	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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			
Emphysema			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	3 / 2993 (0.10%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	17 / 2993 (0.57%)	10 / 2993 (0.33%)	
occurrences causally related to treatment / all	0 / 18	0 / 12	
deaths causally related to treatment / all	0 / 2	0 / 2	
Asphyxia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthma			
subjects affected / exposed	2 / 2993 (0.07%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchitis chronic			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			

subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	27 / 2993 (0.90%)	18 / 2993 (0.60%)	
occurrences causally related to treatment / all	0 / 32	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic respiratory failure			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cough			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	13 / 2993 (0.43%)	14 / 2993 (0.47%)	
occurrences causally related to treatment / all	0 / 13	0 / 17	
deaths causally related to treatment / all	0 / 1	0 / 1	
Dyspnoea exertional			
subjects affected / exposed	3 / 2993 (0.10%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal stenosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pickwickian syndrome			

subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	11 / 2993 (0.37%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 13	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pleurisy			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis aspiration			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary alveolar haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			

subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	5 / 2993 (0.17%)	12 / 2993 (0.40%)	
occurrences causally related to treatment / all	0 / 5	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 3	
Pulmonary fibrosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	6 / 2993 (0.20%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Epistaxis			
subjects affected / exposed	10 / 2993 (0.33%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 10	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			



subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	8 / 2993 (0.27%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 0	
Malignant pleural effusion			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory acidosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory distress			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	9 / 2993 (0.30%)	11 / 2993 (0.37%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 1	
Sleep apnoea syndrome			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal stenosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired diaphragmatic eventration			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial wall thickening			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal pain			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory alkalosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Panic attack			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mania			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal behaviour			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatic symptom disorder			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed anxiety and depressive disorder			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agitation			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Confusional state			

subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion disorder			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eating disorder			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep disorder			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			

subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device fastener issue			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device inappropriate shock delivery			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic liver disease			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			

subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	8 / 2993 (0.27%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	9 / 2993 (0.30%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cholecystitis chronic			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	5 / 2993 (0.17%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cirrhosis alcoholic			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	3 / 2993 (0.10%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic function abnormal			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis alcoholic			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dyskinesia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocholecystis			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic lesion			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive hepatopathy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Biopsy prostate			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood sodium decreased			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoembryonic antigen increased			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerular filtration rate decreased			



subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count increased			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular pressure decreased			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteroscopy			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight increased			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate decreased			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			

subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal function test abnormal			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Occult blood positive			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiogram			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 test positive			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Computerised tomogram heart abnormal			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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			
Alcohol poisoning			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (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	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Jaw fracture			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyphaema			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	9 / 2993 (0.30%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	7 / 2993 (0.23%)	12 / 2993 (0.40%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat stroke			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	4 / 2993 (0.13%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured sacrum			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	17 / 2993 (0.57%)	15 / 2993 (0.50%)	
occurrences causally related to treatment / all	0 / 17	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 1	
Femoral neck fracture			
subjects affected / exposed	9 / 2993 (0.30%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	14 / 2993 (0.47%)	15 / 2993 (0.50%)	
occurrences causally related to treatment / all	0 / 14	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural haematoma			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compression fracture			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon monoxide poisoning			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Burns second degree			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2993 (0.03%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	4 / 2993 (0.13%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary contusion			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	8 / 2993 (0.27%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Snake bite			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			

subjects affected / exposed	4 / 2993 (0.13%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury cervical			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	2 / 2993 (0.07%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subcutaneous haematoma			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	9 / 2993 (0.30%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 4	
Synovial rupture			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (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	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder fracture			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 2993 (0.03%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face injury			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	4 / 2993 (0.13%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Post procedural haemorrhage			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			



subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt stenosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site haematoma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postpericardiotomy syndrome			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	6 / 2993 (0.20%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Upper limb fracture			

subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt aneurysm			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	4 / 2993 (0.13%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin abrasion			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column injury			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			

subjects affected / exposed	3 / 2993 (0.10%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjacent segment degeneration			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniofacial fracture			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal injury			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury of conjunctiva			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye contusion			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Dermoid cyst			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Familial amyloidosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hydrocele			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Janus kinase 2 mutation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina unstable			
subjects affected / exposed	36 / 2993 (1.20%)	38 / 2993 (1.27%)	
occurrences causally related to treatment / all	0 / 38	0 / 43	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	26 / 2993 (0.87%)	17 / 2993 (0.57%)	
occurrences causally related to treatment / all	0 / 30	0 / 23	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	10 / 2993 (0.33%)	14 / 2993 (0.47%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			

subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	5 / 2993 (0.17%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	1 / 2993 (0.03%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	9 / 2993 (0.30%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac amyloidosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac aneurysm			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	11 / 2993 (0.37%)	12 / 2993 (0.40%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 10	0 / 9	
Atrial fibrillation			

subjects affected / exposed	73 / 2993 (2.44%)	77 / 2993 (2.57%)	
occurrences causally related to treatment / all	0 / 101	1 / 95	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	5 / 2993 (0.17%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arrhythmia supraventricular			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	18 / 2993 (0.60%)	18 / 2993 (0.60%)	
occurrences causally related to treatment / all	2 / 20	0 / 18	
deaths causally related to treatment / all	0 / 7	0 / 1	
Cardiac tamponade			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			

subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	6 / 2993 (0.20%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 6	0 / 4	
Sinus bradycardia			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Conduction disorder			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	17 / 2993 (0.57%)	20 / 2993 (0.67%)	
occurrences causally related to treatment / all	0 / 17	0 / 23	
deaths causally related to treatment / all	0 / 1	0 / 2	
Coronary artery occlusion			

subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	8 / 2993 (0.27%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	9 / 2993 (0.30%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 3	0 / 4	
Palpitations			
subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			



subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinoatrial block			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis constrictive			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	3 / 2993 (0.10%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock			
subjects affected / exposed	4 / 2993 (0.13%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Supraventricular extrasystoles			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia paroxysmal			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			

subjects affected / exposed	3 / 2993 (0.10%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Ventricular extrasystoles			
subjects affected / exposed	2 / 2993 (0.07%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	3 / 2993 (0.10%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ventricular tachycardia			
subjects affected / exposed	13 / 2993 (0.43%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 18	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	7 / 2993 (0.23%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pseudoaneurysm			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular deconditioning			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Atrial thrombosis			
subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diastolic dysfunction			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve disease			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve disease			
subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mitral valve disease			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachyarrhythmia			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microvascular coronary artery disease			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	10 / 2993 (0.33%)	12 / 2993 (0.40%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic coronary syndrome			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dilated cardiomyopathy			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral infarction			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	3 / 2993 (0.10%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dementia Alzheimer's type			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	7 / 2993 (0.23%)	12 / 2993 (0.40%)	
occurrences causally related to treatment / all	0 / 7	3 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drop attacks			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Epilepsy			

subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bell's palsy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	3 / 2993 (0.10%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	22 / 2993 (0.74%)	25 / 2993 (0.84%)	
occurrences causally related to treatment / all	1 / 23	2 / 26	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraventricular haemorrhage			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	5 / 2993 (0.17%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Movement disorder			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paralysis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinsonism			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			



subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Quadriplegia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	1 / 2993 (0.03%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Spondylitic myelopathy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	6 / 2993 (0.20%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
Hydrocephalus			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic encephalopathy			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic encephalopathy			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wernicke's encephalopathy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Quadriplegia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal epidural haematoma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar infarction			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular insufficiency			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic intolerance			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral radiculopathy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post cardiac arrest syndrome			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Thoracic radiculopathy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	7 / 2993 (0.23%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of chronic disease			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia macrocytic			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	31 / 2993 (1.04%)	34 / 2993 (1.14%)	
occurrences causally related to treatment / all	0 / 36	2 / 42	
deaths causally related to treatment / all	0 / 0	0 / 2	
Microcytic anaemia			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic haematoma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrogenic anaemia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypochromic anaemia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	6 / 2993 (0.20%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	1 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spontaneous haematoma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo positional			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	5 / 2993 (0.17%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	6 / 2993 (0.20%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 6	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract subcapsular			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic eye disease			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry eye			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular degeneration			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open angle glaucoma			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmoplegia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Age-related macular degeneration			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neovascular age-related macular degeneration			



subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal disorders</b>			
Abdominal discomfort			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal adhesions			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			

subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric polyps			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	10 / 2993 (0.33%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute abdomen			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			

subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	5 / 2993 (0.17%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 5	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental caries			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	6 / 2993 (0.20%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 8	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			

subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal perforation			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastritis			
subjects affected / exposed	3 / 2993 (0.10%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal fistula			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	8 / 2993 (0.27%)	17 / 2993 (0.57%)	
occurrences causally related to treatment / all	0 / 10	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 2	
Gastrointestinal necrosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	5 / 2993 (0.17%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids thrombosed			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			

subjects affected / exposed	14 / 2993 (0.47%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 15	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Intestinal obstruction			
subjects affected / exposed	5 / 2993 (0.17%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis mesenteric vessel			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Melaena			
subjects affected / exposed	1 / 2993 (0.03%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obturator hernia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema mouth			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal achalasia			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal obstruction			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophagitis			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic haemorrhage			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	7 / 2993 (0.23%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis ulcerative			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	3 / 2993 (0.10%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal ulcer haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			



subjects affected / exposed	4 / 2993 (0.13%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenogastric reflux			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive duodenitis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth impacted			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 2993 (0.10%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vomiting			
subjects affected / exposed	3 / 2993 (0.10%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic mass			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	3 / 2993 (0.10%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocutaneous fistula			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Large intestine polyp			
subjects affected / exposed	3 / 2993 (0.10%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired oesophageal web			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland mass			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernial eventration			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal sphincter insufficiency			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bile acid malabsorption			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal stenosis			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated umbilical hernia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal incontinence			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal inflammation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Henoch-Schonlein purpura			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity vasculitis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin erosion			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	6 / 2993 (0.20%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic skin eruption			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	4 / 2993 (0.13%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Anuria			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis haemorrhagic			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	5 / 2993 (0.17%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interacapillary glomerulosclerosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcapsular renal haematoma			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyuria			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	5 / 2993 (0.17%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 5	3 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal infarct			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	3 / 2993 (0.10%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract disorder			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			

subjects affected / exposed	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postrenal failure			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal injury			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	11 / 2993 (0.37%)	10 / 2993 (0.33%)	
occurrences causally related to treatment / all	5 / 11	5 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis noninfective			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	6 / 2993 (0.20%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			



subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	28 / 2993 (0.94%)	54 / 2993 (1.80%)	
occurrences causally related to treatment / all	5 / 30	16 / 56	
deaths causally related to treatment / all	0 / 0	0 / 1	
Prerenal failure			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cushing's syndrome			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Joint swelling			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Arthralgia			
subjects affected / exposed	7 / 2993 (0.23%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	4 / 2993 (0.13%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	8 / 2993 (0.27%)	10 / 2993 (0.33%)	
occurrences causally related to treatment / all	1 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility decreased			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck mass			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	4 / 2993 (0.13%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle haemorrhage			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	3 / 2993 (0.10%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			

subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	11 / 2993 (0.37%)	9 / 2993 (0.30%)	
occurrences causally related to treatment / all	0 / 13	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthrititis			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scleroderma			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	6 / 2993 (0.20%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma muscle			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Connective tissue inflammation			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Connective tissue disorder			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immobilisation syndrome			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2993 (0.00%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	5 / 2993 (0.17%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			

subjects affected / exposed	2 / 2993 (0.07%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	11 / 2993 (0.37%)	13 / 2993 (0.43%)	
occurrences causally related to treatment / all	0 / 15	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchopulmonary aspergillosis allergic			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	24 / 2993 (0.80%)	17 / 2993 (0.57%)	
occurrences causally related to treatment / all	0 / 25	0 / 18	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dacryocystitis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	4 / 2993 (0.13%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalomyelitis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endocarditis staphylococcal			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	4 / 2993 (0.13%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Fournier's gangrene			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gangrene			
subjects affected / exposed	6 / 2993 (0.20%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gas gangrene			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			



subjects affected / exposed	6 / 2993 (0.20%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			

subjects affected / exposed	7 / 2993 (0.23%)	6 / 2993 (0.20%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nasopharyngitis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	4 / 2993 (0.13%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis chronic			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic inflammatory disease			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	3 / 2993 (0.10%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Peritonsillar abscess			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	110 / 2993 (3.68%)	87 / 2993 (2.91%)	
occurrences causally related to treatment / all	0 / 116	0 / 98	
deaths causally related to treatment / all	0 / 13	0 / 15	
Pneumonia aspiration			
subjects affected / exposed	5 / 2993 (0.17%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Pneumonia influenzal			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia moraxella			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pseudomonal			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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	5 / 2993 (0.17%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Influenza			
subjects affected / exposed	5 / 2993 (0.17%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tuberculosis of intrathoracic lymph nodes			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	4 / 2993 (0.13%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	26 / 2993 (0.87%)	29 / 2993 (0.97%)	
occurrences causally related to treatment / all	0 / 28	0 / 31	
deaths causally related to treatment / all	0 / 2	0 / 0	
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic abscess			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyoderma			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyonephrosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonellosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	16 / 2993 (0.53%)	25 / 2993 (0.84%)	
occurrences causally related to treatment / all	1 / 16	0 / 25	
deaths causally related to treatment / all	0 / 3	0 / 9	
Septic arthritis staphylococcal			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Septic shock			
subjects affected / exposed	9 / 2993 (0.30%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 3	
Skin infection			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subacute endocarditis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculous pleurisy			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	5 / 2993 (0.17%)	5 / 2993 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Biliary sepsis			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	2 / 2993 (0.07%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Abscess limb			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	6 / 2993 (0.20%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Coronavirus infection			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Escherichia urinary tract infection			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida pneumonia			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Citrobacter sepsis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Clostridium difficile infection			
subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Helicobacter infection			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdiaphragmatic abscess			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysematous cystitis			



subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoas abscess			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	5 / 2993 (0.17%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Infective tenosynovitis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective staphylococcal			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus infection			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			

subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal abscess			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	6 / 2993 (0.20%)	7 / 2993 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Clostridial infection			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis bacterial			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			

subjects affected / exposed	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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	10 / 2993 (0.33%)	8 / 2993 (0.27%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cholecystitis infective			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective spondylitis			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acarodermatitis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis bacterial			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue abscess			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella urinary tract infection			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Norovirus infection			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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 sepsis			

subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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	0 / 2993 (0.00%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
COVID-19 pneumonia			
subjects affected / exposed	30 / 2993 (1.00%)	28 / 2993 (0.94%)	
occurrences causally related to treatment / all	0 / 30	0 / 28	
deaths causally related to treatment / all	0 / 9	0 / 7	
Diverticulitis intestinal perforated			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	71 / 2993 (2.37%)	69 / 2993 (2.31%)	
occurrences causally related to treatment / all	0 / 73	0 / 69	
deaths causally related to treatment / all	0 / 14	0 / 4	
Infected gouty tophus			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			
subjects affected / exposed	1 / 2993 (0.03%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
H3N2 influenza			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary paracoccidioidomycosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic infection			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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 / 2993 (0.03%)	0 / 2993 (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	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningoencephalitis viral			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida infection			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal endocarditis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (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			
Hypervolaemia			

subjects affected / exposed	3 / 2993 (0.10%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alkalosis hypochloraemic			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	2 / 2993 (0.07%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dehydration			
subjects affected / exposed	6 / 2993 (0.20%)	14 / 2993 (0.47%)	
occurrences causally related to treatment / all	0 / 8	1 / 16	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetes mellitus			
subjects affected / exposed	3 / 2993 (0.10%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			

subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	8 / 2993 (0.27%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	2 / 10	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	1 / 2993 (0.03%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	6 / 2993 (0.20%)	19 / 2993 (0.63%)	
occurrences causally related to treatment / all	4 / 7	15 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypernatraemia			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	9 / 2993 (0.30%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 11	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	3 / 2993 (0.10%)	10 / 2993 (0.33%)	
occurrences causally related to treatment / all	1 / 5	4 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			



subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Marasmus			
subjects affected / exposed	1 / 2993 (0.03%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metabolic acidosis			
subjects affected / exposed	2 / 2993 (0.07%)	2 / 2993 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mineral metabolism disorder			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (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	2 / 2993 (0.07%)	0 / 2993 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	3 / 2993 (0.10%)	4 / 2993 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic metabolic decompensation			

subjects affected / exposed	3 / 2993 (0.10%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adult failure to thrive			
subjects affected / exposed	0 / 2993 (0.00%)	1 / 2993 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	1 / 2993 (0.03%)	3 / 2993 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
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>	Placebo	Finerenone	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1228 / 2993 (41.03%)	1317 / 2993 (44.00%)	
Investigations			
Glomerular filtration rate decreased			
subjects affected / exposed	107 / 2993 (3.58%)	156 / 2993 (5.21%)	
occurrences (all)	144	219	
Vascular disorders			
Hypotension			
subjects affected / exposed	128 / 2993 (4.28%)	210 / 2993 (7.02%)	
occurrences (all)	143	240	
Hypertension			
subjects affected / exposed	179 / 2993 (5.98%)	103 / 2993 (3.44%)	
occurrences (all)	215	121	
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	168 / 2993 (5.61%)	116 / 2993 (3.88%)	
occurrences (all)	218	143	
Nervous system disorders			
Dizziness			

subjects affected / exposed occurrences (all)	137 / 2993 (4.58%) 158	170 / 2993 (5.68%) 198	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	162 / 2993 (5.41%) 178	169 / 2993 (5.65%) 193	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	129 / 2993 (4.31%) 157	167 / 2993 (5.58%) 208	
Renal and urinary disorders Renal impairment subjects affected / exposed occurrences (all)	110 / 2993 (3.68%) 127	193 / 2993 (6.45%) 232	
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all)  COVID-19 subjects affected / exposed occurrences (all)	149 / 2993 (4.98%) 194  297 / 2993 (9.92%) 318	150 / 2993 (5.01%) 184  292 / 2993 (9.76%) 301	
Metabolism and nutrition disorders Hyperkalaemia subjects affected / exposed occurrences (all)  Hypokalaemia subjects affected / exposed occurrences (all)	107 / 2993 (3.58%) 139  196 / 2993 (6.55%) 255	252 / 2993 (8.42%) 348  88 / 2993 (2.94%) 105	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 September 2020	addressed requests from health authorities
16 May 2022	altered certain secondary efficacy endpoints of the study: • The secondary efficacy variable on sustained eGFR decrease was changed from $\geq 40\%$ to $\geq 50\%$ based on data from the FIGARO-DKD and FIDELIO-DKD studies. • Change in NYHA class from baseline was removed from exploratory endpoints. Total HF events and improvement in NYHA class from baseline to Month 12 were added as secondary endpoints due to their clinical significance. • Change in UACR from baseline and time to first occurrence of the following composite endpoint: sustained decrease in eGFR $\geq 57\%$ relative to baseline over at least 4 weeks, or sustained eGFR decline to $<15$ mL/min/1.73 m <sup>2</sup> or initiation of dialysis or renal transplantation, were added as exploratory endpoints to compare the results with existing data from FIGARO-DKD and FIDELIO-DKD.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported