Clinical trial results:
An International, Double-blind, Randomised, Placebo-Controlled Phase IIIb Study to Evaluate the Effect of Dapagliflozin on Reducing CV Death or Worsening Heart Failure in Patients with Heart Failure with Preserved Ejection Fraction (HFpEF).

DELIVER - Dapagliflozin Evaluation to Improve the LIVEs of Patients with PReserved Ejection Fraction Heart Failure

Summary

EudraCT number	2018-000802-46
Trial protocol	CZ NL ES PL HU BE RO
Global end of trial date	27 March 2022

Results information

Result version number	v1 (current)
This version publication date	01 April 2023
First version publication date	01 April 2023

Trial information

Trial identification

Sponsor protocol code	D169CC00001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	Vastra Malarehamnen 9, Södertälje, Sweden, 151 85
Public contact	Global Clinical Lead, AstraZeneca AB, +1 877-240-9479, Information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca AB, +1 877-240-9479, Information.center@astrazeneca.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	27 March 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 March 2022
Global end of trial reached?	Yes
Global end of trial date	27 March 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine whether dapagliflozin is superior to placebo, when added to standard of care, in reducing the composite of CV death and HF events (hospitalisation for HF or urgent HF visit) in patients with HF and preserved systolic function in

- full study population

- subpopulation with LVEF <60%

Protection of trial subjects:

N/A

Background therapy:

Patients included in DELIVER were treated according to local guideline recommended therapy for HF symptoms (eg, diuretics) and co-morbidities (including treatment for hypertension, ischaemic heart disease, and atrial fibrillation, diabetes, hyperlipidaemia).

Evidence for comparator:

Placebo was selected as the control treatment because at the time of study initiation there was no approved pharmacological intervention for HF and LVEF > 40% that could be used as a comparator.

Actual start date of recruitment	27 August 2018
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	Argentina: 320
Country: Number of subjects enrolled	Belgium: 64
Country: Number of subjects enrolled	Brazil: 405
Country: Number of subjects enrolled	Bulgaria: 493
Country: Number of subjects enrolled	Canada: 299
Country: Number of subjects enrolled	China: 310
Country: Number of subjects enrolled	Czechia: 274
Country: Number of subjects enrolled	Hungary: 466
Country: Number of subjects enrolled	Japan: 422
Country: Number of subjects enrolled	Mexico: 216

Country: Number of subjects enrolled	Netherlands: 176
Country: Number of subjects enrolled	Peru: 240
Country: Number of subjects enrolled	Poland: 572
Country: Number of subjects enrolled	Romania: 61
Country: Number of subjects enrolled	Russian Federation: 401
Country: Number of subjects enrolled	Saudi Arabia: 190
Country: Number of subjects enrolled	Spain: 308
Country: Number of subjects enrolled	Taiwan: 318
Country: Number of subjects enrolled	United States: 552
Country: Number of subjects enrolled	Viet Nam: 176
Worldwide total number of subjects	6263
EEA total number of subjects	2414

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)	1345
From 65 to 84 years	4466
85 years and over	452

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

At the first visit, i.e. the enrollment visit 1, patients were evaluated regarding the protocol mandated inclusion and exclusion criteria.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Dapa 10 mg

Arm description:

Dapagliflozin 10 mg tablets administered once daily per oral use

Arm type	Active comparator
Investigational medicinal product name	Dapagliflozin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dapagliflozin 10 mg tablets administered orally once daily

Arm title	Placebo

Arm description:

Placebo tablet to match dapagliflozin 10 mg, given once daily per oral use

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

Dosage and administration details:

Matching placebo for dapagliflozin 10 mg tablets administered orally once daily

Number of subjects in period 1	Dapa 10 mg	Placebo
Started	3131	3132
Completed	3121	3121
Not completed	10	11
Consent withdrawn by subject	8	10

Lost to follow-up	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Dapa 10 mg
Reporting group description:	
Dapagliflozin 10 mg tablets administered once daily per oral use	
Reporting group title	Placebo
Reporting group description:	
Placebo tablet to match dapagliflozin 10 mg, given once daily per oral use	

Reporting group values	Dapa 10 mg	Placebo	Total
Number of subjects	3131	3132	6263
Age Categorical Units: Participants			
<= 50	85	74	159
> 50	3046	3058	6104
Age Continuous Units: Years			
arithmetic mean	71.8	71.5	
standard deviation	± 9.6	± 9.5	-
Sex: Female, Male Units: Participants			
Female	1364	1383	2747
Male	1767	1749	3516
Age, Customized Units: Subjects			
<= 65	743	761	1504
>65 - 75	1184	1228	2412
> 75	1204	1143	2347
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	632	598	1230
Not Hispanic or Latino	2499	2534	5033
Unknown or Not Reported	0	0	0
Race/Ethnicity, Customized Units: Subjects			
White	2214	2225	4439
Black or African American	81	78	159
Asian	630	644	1274
Native Hawaiian or other Pacific Islander	0	0	0
American Indian or Alaska Native	93	96	189
Other	113	89	202
Prior HF Hospitalization Units: Subjects			
Yes	1270	1269	2539
No	1861	1863	3724
NYHA Class at Baseline Units: Subjects			

NYHA class I	0	1	1
NYHA class II	2314	2399	4713
NYHA class III	807	724	1531
NYHA class IV	10	8	18
Medical History of Type 2 Diabetes Units: Subjects			
Yes	1401	1405	2806
No	1730	1727	3457
LVEF (%) at Baseline Units: Percentage of blood leaving the heart			
arithmetic mean	54.0	54.3	
standard deviation	± 8.6	± 8.9	-

End points

End points reporting groups	
Reporting group title	Dapa 10 mg
Reporting group description: Dapagliflozin 10 mg tablets administered once daily per oral use	
Reporting group title	Placebo
Reporting group description: Placebo tablet to match dapagliflozin 10 mg, given once daily per oral use	

Primary: Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure	
End point title	Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure
End point description: Dual primary efficacy Primary endpoint analysed in all patients randomised (Full analysis set)	
End point type	Primary
End point timeframe: Up to 42.1 months	

End point values	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3131	3132		
Units: Participants				
Number of participants with an event	512	610		

Statistical analyses

Statistical analysis title	Cox regression
Statistical analysis description: Comparison Group: Placebo	
Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	6263
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.0008
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.82

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.92

Notes:

[1] - Analysed in all randomized patients

Primary: Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure for LVEF <60% subpopulation

End point title	Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure for LVEF <60% subpopulation

End point description:

Dual primary efficacy

Primary endpoint analysed in all patients randomised with LVEF < 60% at baseline

End point type	Primary

End point timeframe:

Up to 42.1 months

End point values	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2200	2172		
Units: Participants				
Number of participants with an event	381	440		

Statistical analyses

Statistical analysis title	Cox regression

Statistical analysis description:

Comparison Group: Placebo

Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	4372
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.0085
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.95

Notes:

[2] - Analysed in all randomized patients with LVEF < 60% at baseline

Secondary: Events included in the Composite Endpoint of CV Death or Recurrent Heart Failure Event (Hospitalization due to Heart Failure or Urgent Heart Failure Visit)

End point title	Events included in the Composite Endpoint of CV Death or Recurrent Heart Failure Event (Hospitalization due to Heart Failure or Urgent Heart Failure Visit)

End point description:

Secondary efficacy

Total number of heart failure events (first and recurrent) and cardiovascular death, analysed in all randomized patients

End point type	Secondary

End point timeframe:

Up to 42.1 months

End point values	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3131	3132		
Units: Number of events	815	1057		

Statistical analyses

Statistical analysis title	Recurrent event analysis

Statistical analysis description:

Comparison Group: Placebo

Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	6263
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.0003
Method	LWYY proportional rates model
Parameter estimate	Rate Ratio (RR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.89

Notes:

[3] - Analysed in all randomized patients

Secondary: Events included in the Composite Endpoint of CV Death or Recurrent Heart Failure Event (Hospitalization due to Heart Failure or Urgent Heart Failure Visit) for LVEF <60% subpopulation

End point title	Events included in the Composite Endpoint of CV Death or Recurrent Heart Failure Event (Hospitalization due to Heart Failure or Urgent Heart Failure Visit) for LVEF <60% subpopulation

End point description:

Secondary efficacy

Total number of heart failure events (first and recurrent) and cardiovascular death, analysed in all randomized patients with LVEF < 60% at baseline

End point type	Secondary

End point timeframe:

Up to 42.1 months

End point values	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2200	2172		
Units: Number of events	605	782		

Statistical analyses

Statistical analysis title	Recurrent event analysis

Statistical analysis description:

Comparison Group: Placebo

Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	4372
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	= 0.0017
Method	LWYY proportional rates model
Parameter estimate	Rate Ratio (RR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.9

Notes:

[4] - Analysed in all randomized patients with LVEF < 60% at baseline

Secondary: Subjects Included in the Endpoint of Cardiovascular Death

End point title	Subjects Included in the Endpoint of Cardiovascular Death

End point description:

Secondary efficacy

End point type	Secondary

End point timeframe:

Up to 42.1 months

End point values	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3131	3132		
Units: Participants				
Number of participants with an event	231	261		

Statistical analyses

Statistical analysis title	Cox regression
Statistical analysis description:	
Comparison Group: Placebo	
Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	6263
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1678
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.05

Secondary: Change From Baseline in the KCCQ Total Symptom Score at 8 Months

End point title	Change From Baseline in the KCCQ Total Symptom Score at 8 Months
End point description:	
KCCQ is a 23-item, self-administered instrument that quantifies physical function, symptoms (frequency, severity and recent change), social function, self-efficacy and knowledge, and quality of life. The KCCQ Total Symptom Score incorporates the symptom domains into a single score. Scores are transformed to a range of 0-100, in which higher scores reflect better health status.	
End point type	Secondary
End point timeframe:	
Baseline and 8 months or death before 8 months	

End point values	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1316	1311		
Units: Scores on a scale				
arithmetic mean (standard deviation)	8.3 (± 20.3)	5.2 (± 21.1)		

Statistical analyses

Statistical analysis title	Win ratio analysis
Statistical analysis description: Comparison Group: Placebo	
Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	2627
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	= 0.0086 [6]
Method	Win Ratio
Parameter estimate	Rate Ratio (RR)
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.03
upper limit	1.21

Notes:

[5] - Full analysis set population, including only assessments performed or planned prior to March 11th, 2020, when COVID-19 was declared a pandemic by the WHO.
[6] - The p-value is obtained from a rank ANCOVA adjusted for baseline KCCQ score, stratified by T2DM status at randomisation.

Secondary: Subjects Included in the Endpoint of All-cause Mortality

End point title	Subjects Included in the Endpoint of All-cause Mortality
End point description: Secondary efficacy	
End point type	Secondary
End point timeframe: Up to 42.1 months	

End point values	Dapa 10 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3131	3132		
Units: Participants				
Number of participants with an event	497	526		

Statistical analyses

Statistical analysis title	Cox regression
Statistical analysis description: Comparison Group: Placebo	
Comparison groups	Dapa 10 mg v Placebo
Number of subjects included in analysis	6263
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3425
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.07

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug until last study visit

Adverse event reporting additional description:

Safety analysis set: randomized patients who received at least 1 dose of study drug

Systematic: Serious AEs, AEs leading to discont. / amput. or preceding events / potential endpoint / interruption of study drug, non-serious AEs: MI, unstable angina, stroke, major hypoglycaemic events, potential DKAs and amput.

Non-systematic: Other AEs

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Dapa 10 mg

Reporting group description:

Dapagliflozin 10 mg tablets administered once daily per oral use

Reporting group title	Placebo

Reporting group description:

Placebo tablet to match dapagliflozin 10 mg, given once daily per oral use

Serious adverse events	Dapa 10 mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1454 / 3126 (46.51%)	1508 / 3127 (48.23%)	
number of deaths (all causes)	509	532	
number of deaths resulting from adverse events	507	529	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adrenal gland cancer metastatic			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
B-cell lymphoma			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute leukaemia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma of colon			
subjects affected / exposed	6 / 3126 (0.19%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 6	1 / 4	
deaths causally related to treatment / all	0 / 3	0 / 1	
Adrenal neoplasm			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			

subjects affected / exposed	4 / 3126 (0.13%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bile duct cancer			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	1 / 3126 (0.03%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer recurrent			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			

subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Breast cancer			
subjects affected / exposed	2 / 3126 (0.06%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer metastatic			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer recurrent			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial carcinoma			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cervix carcinoma			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myelomonocytic leukaemia			

subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Gastric neoplasm			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colon cancer			
subjects affected / exposed	6 / 3126 (0.19%)	9 / 3127 (0.29%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 2	
Colon cancer metastatic			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer recurrent			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colon neoplasm			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer metastatic			

subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Endometrial cancer			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer metastatic			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Essential thrombocythaemia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fallopian tube cancer			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicular lymphoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	3 / 3126 (0.10%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colon adenoma			

subjects affected / exposed	4 / 3126 (0.13%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal lymphoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic cancer			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatocellular carcinoma			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Intracranial meningioma malignant			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			

subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint neoplasm			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	3 / 3126 (0.10%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Lung cancer metastatic			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Lung neoplasm			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	4 / 3126 (0.13%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 4	0 / 3	
Gastrointestinal tract adenoma			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm prostate			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myeloproliferative neoplasm			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal carcinoma			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Oesophageal neoplasm			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lymphoplasmacytoid lymphoma/immunocytoma			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoproliferative disorder			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	4 / 3126 (0.13%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of unknown primary site			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mediastinum neoplasm			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to bone			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to liver			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic carcinoma of the bladder			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic gastric cancer			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			

subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	3 / 3126 (0.10%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ovarian neoplasm			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	3 / 3126 (0.10%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 2	
Pancreatic neoplasm			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Parathyroid tumour benign			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmacytoma			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural mesothelioma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Prostate cancer			
subjects affected / exposed	5 / 3126 (0.16%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Prostate cancer recurrent			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	3 / 3126 (0.10%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Rectal cancer			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal neoplasm			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Refractory cytopenia with unilineage dysplasia			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Ovarian cancer metastatic				
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
Renal cancer metastatic				
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
Tumour associated fever				
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Sarcoma				
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Seborrhoeic keratosis				
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Small cell lung cancer				
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
Small cell lung cancer extensive stage				
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Small intestine carcinoma				

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue neoplasm			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (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	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous cell carcinoma of the vulva			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Thyroid cancer			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Triple negative breast cancer			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Renal neoplasm				
subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)		
occurrences causally related to treatment / all	0 / 3	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Tumour embolism				
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Uterine cancer				
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
Uterine neoplasm				
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Waldenstrom's macroglobulinaemia				
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 1		
Tumour perforation				
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
Lung squamous cell carcinoma stage IV				
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 1		
Adult T-cell lymphoma/leukaemia				

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diffuse large B-cell lymphoma			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lung adenocarcinoma stage I			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer stage IV			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Haematoma			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic dissection			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			

subjects affected / exposed	4 / 3126 (0.13%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bleeding varicose vein			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
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	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery embolism			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematocoele			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	4 / 3126 (0.13%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	10 / 3126 (0.32%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	3 / 10	0 / 6	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Iliac artery stenosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoedema			

subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	3 / 3126 (0.10%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	24 / 3126 (0.77%)	18 / 3127 (0.58%)	
occurrences causally related to treatment / all	0 / 24	2 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	4 / 3126 (0.13%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	14 / 3126 (0.45%)	9 / 3127 (0.29%)	
occurrences causally related to treatment / all	0 / 16	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			

subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular insufficiency			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vessel perforation			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	5 / 3126 (0.16%)	9 / 3127 (0.29%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
subjects affected / exposed	54 / 3126 (1.73%)	52 / 3127 (1.66%)	
occurrences causally related to treatment / all	0 / 54	0 / 52	
deaths causally related to treatment / all	0 / 54	0 / 52	
Asthenia			
subjects affected / exposed	5 / 3126 (0.16%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac death			
subjects affected / exposed	3 / 3126 (0.10%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 3	
Catheter site pain			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			

subjects affected / exposed	7 / 3126 (0.22%)	9 / 3127 (0.29%)	
occurrences causally related to treatment / all	1 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural failure			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic cardiac valve thrombosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Feeling abnormal			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypothermia			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	1 / 3126 (0.03%)	0 / 3127 (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	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site joint inflammation			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multimorbidity			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	3 / 3126 (0.10%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Non-cardiac chest pain			

subjects affected / exposed	7 / 3126 (0.22%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema due to cardiac disease			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	26 / 3126 (0.83%)	37 / 3127 (1.18%)	
occurrences causally related to treatment / all	1 / 26	1 / 37	
deaths causally related to treatment / all	1 / 26	1 / 37	
Sudden death			
subjects affected / exposed	24 / 3126 (0.77%)	26 / 3127 (0.83%)	
occurrences causally related to treatment / all	0 / 24	0 / 26	
deaths causally related to treatment / all	0 / 24	0 / 26	
Ulcer haemorrhage			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent-graft endoleak			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Amyloidosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast media allergy			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart transplant rejection			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary amyloidosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Cardiac assistance device user			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired phimosis			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Breast mass			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial atrophy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heavy menstrual bleeding			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermenstrual bleeding			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal ulcer			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal inflammation			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			

subjects affected / exposed	4 / 3126 (0.13%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	16 / 3126 (0.51%)	17 / 3127 (0.54%)	
occurrences causally related to treatment / all	0 / 19	0 / 20	
deaths causally related to treatment / all	0 / 9	0 / 6	
Acute pulmonary oedema			
subjects affected / exposed	8 / 3126 (0.26%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 2	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergic respiratory symptom			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	3 / 3126 (0.10%)	9 / 3127 (0.29%)	
occurrences causally related to treatment / all	0 / 4	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choking			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	21 / 3126 (0.67%)	18 / 3127 (0.58%)	
occurrences causally related to treatment / all	1 / 30	0 / 26	
deaths causally related to treatment / all	0 / 3	0 / 2	
Chronic respiratory disease			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic respiratory failure			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cough			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	3 / 3126 (0.10%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Interstitial lung disease			
subjects affected / exposed	3 / 3126 (0.10%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	1 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	5 / 3126 (0.16%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 2	
Lung disorder			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung opacity			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nocturnal dyspnoea			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platypnoea			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	8 / 3126 (0.26%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pleurisy			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	11 / 3126 (0.35%)	9 / 3127 (0.29%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 3	0 / 5	
Pulmonary fibrosis			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pulmonary hilum mass			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary hypertension			

subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal stenosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory failure			
subjects affected / exposed	10 / 3126 (0.32%)	17 / 3127 (0.54%)	
occurrences causally related to treatment / all	0 / 11	0 / 19	
deaths causally related to treatment / all	0 / 2	0 / 9	
Sleep apnoea syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sputum retention			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Psychiatric disorders			
Delusion			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Confusional state			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium tremens			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	2 / 3126 (0.06%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organic brain syndrome			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychogenic respiratory distress			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychomotor retardation			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance abuse			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device failure			

subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device power source issue			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device fastener issue			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	4 / 3126 (0.13%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	8 / 3126 (0.26%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	1 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	3 / 3126 (0.10%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	5 / 3126 (0.16%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive hepatopathy			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	2 / 3126 (0.06%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hepatic failure			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic mass			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic vein thrombosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis alcoholic			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Investigations			
Blood creatinine increased			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral pulse decreased			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus disease activity index abnormal			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QRS complex prolonged			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 antibody test positive			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrin D dimer increased			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Burns third degree			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Abdominal injury			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wound dehiscence			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	4 / 3126 (0.13%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula site complication			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back injury			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (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	10 / 3126 (0.32%)	11 / 3127 (0.35%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Comminuted fracture			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compression fracture			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary bypass stenosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			

subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eschar			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye injury			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	5 / 3126 (0.16%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	6 / 3126 (0.19%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured sacrum			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	0 / 3126 (0.00%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 2	
Heat illness			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	10 / 3126 (0.32%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	1 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Humerus fracture			
subjects affected / exposed	3 / 3126 (0.10%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated incisional hernia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site haemorrhage			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			

subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	0 / 3126 (0.00%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open fracture			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penis injury			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic fracture			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Post procedural complication			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Post procedural haematoma			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural hypotension			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural myocardial infarction			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural swelling			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic pain			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative respiratory failure			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Procedural pain			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pneumothorax			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			

subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Skin laceration			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	11 / 3126 (0.35%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 11	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Stomal hernia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			

subjects affected / exposed	4 / 3126 (0.13%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Subdural haemorrhage			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	0 / 3126 (0.00%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Repetitive strain injury			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft occlusion			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft stenosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft thrombosis			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (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	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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			
Congenital hypercoagulation			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patent ductus arteriosus			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal arteriovenous malformation			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute coronary syndrome			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Acute left ventricular failure			
subjects affected / exposed	10 / 3126 (0.32%)	16 / 3127 (0.51%)	
occurrences causally related to treatment / all	0 / 12	0 / 19	
deaths causally related to treatment / all	0 / 2	0 / 2	
Acute myocardial infarction			
subjects affected / exposed	63 / 3126 (2.02%)	63 / 3127 (2.01%)	
occurrences causally related to treatment / all	3 / 73	0 / 71	
deaths causally related to treatment / all	0 / 8	0 / 8	
Acute right ventricular failure			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	18 / 3126 (0.58%)	19 / 3127 (0.61%)	
occurrences causally related to treatment / all	0 / 20	1 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	49 / 3126 (1.57%)	62 / 3127 (1.98%)	
occurrences causally related to treatment / all	1 / 56	0 / 75	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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 / 3126 (0.03%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	1 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arrhythmia supraventricular			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrial flutter			
subjects affected / exposed	10 / 3126 (0.32%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	6 / 3126 (0.19%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial thrombosis			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			

subjects affected / exposed	7 / 3126 (0.22%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular dissociation			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	11 / 3126 (0.35%)	13 / 3127 (0.42%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac amyloidosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	18 / 3126 (0.58%)	17 / 3127 (0.54%)	
occurrences causally related to treatment / all	1 / 18	0 / 17	
deaths causally related to treatment / all	1 / 17	0 / 15	
Atrial fibrillation			

subjects affected / exposed	69 / 3126 (2.21%)	57 / 3127 (1.82%)	
occurrences causally related to treatment / all	2 / 82	1 / 62	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	308 / 3126 (9.85%)	377 / 3127 (12.06%)	
occurrences causally related to treatment / all	10 / 458	5 / 581	
deaths causally related to treatment / all	1 / 61	0 / 61	
Cardiac failure acute			
subjects affected / exposed	57 / 3126 (1.82%)	63 / 3127 (2.01%)	
occurrences causally related to treatment / all	2 / 73	2 / 90	
deaths causally related to treatment / all	1 / 7	0 / 4	
Cardiac failure chronic			
subjects affected / exposed	23 / 3126 (0.74%)	26 / 3127 (0.83%)	
occurrences causally related to treatment / all	3 / 32	3 / 44	
deaths causally related to treatment / all	1 / 5	0 / 5	
Cardiac failure congestive			
subjects affected / exposed	63 / 3126 (2.02%)	82 / 3127 (2.62%)	
occurrences causally related to treatment / all	1 / 86	5 / 116	
deaths causally related to treatment / all	0 / 5	0 / 18	
Cardiac failure high output			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve disease			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiorenal syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			

subjects affected / exposed	3 / 3126 (0.10%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 5	
Cardiogenic shock			
subjects affected / exposed	9 / 3126 (0.29%)	12 / 3127 (0.38%)	
occurrences causally related to treatment / all	0 / 9	1 / 12	
deaths causally related to treatment / all	0 / 6	1 / 8	
Cardiomegaly			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiomyopathy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiomyopathy alcoholic			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	3 / 3126 (0.10%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 3	
Cardiac ventricular thrombosis			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular insufficiency			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mitral valve disease			

subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chronic left ventricular failure			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	9 / 3126 (0.29%)	14 / 3127 (0.45%)	
occurrences causally related to treatment / all	0 / 9	0 / 16	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	3 / 3126 (0.10%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frederick's syndrome			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve incompetence			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive cardiomyopathy			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	5 / 3126 (0.16%)	8 / 3127 (0.26%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 1	
Microvascular coronary artery disease			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve calcification			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic coronary syndrome			
subjects affected / exposed	3 / 3126 (0.10%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	15 / 3126 (0.48%)	18 / 3127 (0.58%)	
occurrences causally related to treatment / all	0 / 16	0 / 19	
deaths causally related to treatment / all	0 / 8	0 / 12	
Myocardial fibrosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myxomatous mitral valve degeneration			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal rhythm			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinoatrial block			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			

subjects affected / exposed	9 / 3126 (0.29%)	11 / 3127 (0.35%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	8 / 3126 (0.26%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve stenosis			
subjects affected / exposed	0 / 3126 (0.00%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	2 / 3126 (0.06%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia induced cardiomyopathy			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trifascicular block			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	6 / 3126 (0.19%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	1 / 6	1 / 6	
deaths causally related to treatment / all	0 / 4	1 / 2	
Ventricular tachycardia			
subjects affected / exposed	13 / 3126 (0.42%)	13 / 3127 (0.42%)	
occurrences causally related to treatment / all	0 / 15	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ventricular arrhythmia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Brain stem infarction			
subjects affected / exposed	5 / 3126 (0.16%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 5	1 / 1	
deaths causally related to treatment / all	0 / 3	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery thrombosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral arteriosclerosis			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Embolic cerebral infarction			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Drop attacks			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	7 / 3126 (0.22%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 7	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	5 / 3126 (0.16%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed level of consciousness			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cubital tunnel syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical cord compression			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular disorder			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	5 / 3126 (0.16%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 5	1 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cerebral infarction			
subjects affected / exposed	11 / 3126 (0.35%)	11 / 3127 (0.35%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 4	
Cerebral haemorrhage			
subjects affected / exposed	2 / 3126 (0.06%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Lacunar infarction			

subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal dyscognitive seizures			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lacunar stroke			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	10 / 3126 (0.32%)	9 / 3127 (0.29%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 5	0 / 4	
Hemiparesis			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			

subjects affected / exposed	3 / 3126 (0.10%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Hypoaesthesia			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intracranial haematoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	70 / 3126 (2.24%)	65 / 3127 (2.08%)	
occurrences causally related to treatment / all	1 / 76	3 / 70	
deaths causally related to treatment / all	0 / 17	0 / 15	
Presyncope			
subjects affected / exposed	4 / 3126 (0.13%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Quadriparesis			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myoclonic epilepsy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myoclonus			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myxoedema coma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	0 / 3126 (0.00%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Parkinsonism			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy alcoholic			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post stroke epilepsy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic stroke			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic encephalopathy			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	6 / 3126 (0.19%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic infarction			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	18 / 3126 (0.58%)	21 / 3127 (0.67%)	
occurrences causally related to treatment / all	0 / 18	1 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Spondylitic myelopathy			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stroke			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	5 / 3126 (0.16%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uraemic encephalopathy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar stroke			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia macrocytic			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	16 / 3126 (0.51%)	24 / 3127 (0.77%)	
occurrences causally related to treatment / all	0 / 18	0 / 26	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood loss anaemia			
subjects affected / exposed	4 / 3126 (0.13%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic cyst			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deficiency anaemia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Evans syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic anaemia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocoagulable state			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	3 / 3126 (0.10%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrogenic anaemia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	2 / 3126 (0.06%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Meniere's disease			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Epiretinal membrane			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lens dislocation			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Age-related macular degeneration			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amaurosis fugax			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	10 / 3126 (0.32%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular rupture			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous opacities			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Chronic gastritis			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal adhesions			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal incarcerated hernia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			

subjects affected / exposed	0 / 3126 (0.00%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute abdomen			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Anal haemorrhage			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 3126 (0.00%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			

subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	1 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	3 / 3126 (0.10%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			

subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (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	1 / 3126 (0.03%)	8 / 3127 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive duodenitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal vascular malformation haemorrhagic			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric perforation			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric polyps			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	3 / 3126 (0.10%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	3 / 3126 (0.10%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
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	14 / 3126 (0.45%)	15 / 3127 (0.48%)	
occurrences causally related to treatment / all	0 / 14	0 / 17	
deaths causally related to treatment / all	0 / 3	0 / 0	
Gastrointestinal motility disorder			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal necrosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal perforation			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal polyp haemorrhage			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric antral vascular ectasia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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 / 3126 (0.00%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			

subjects affected / exposed	1 / 3126 (0.03%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haematochezia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoperitoneum			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic erosive gastritis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 3126 (0.00%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal perforation			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	6 / 3126 (0.19%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia strangulated			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	0 / 3126 (0.00%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Haematemesis			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haematoma			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haemorrhage			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic enteritis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	1 / 3126 (0.03%)	11 / 3127 (0.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	5 / 3126 (0.16%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mechanical ileus			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric haemorrhage			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal obstruction			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic duct dilatation			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	2 / 3126 (0.06%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tooth impacted			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia, obstructive			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			

subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal polyp			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retching			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland calculus			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated umbilical hernia			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress ulcer			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			

subjects affected / exposed	4 / 3126 (0.13%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cutaneous vasculitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis atopic			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	3 / 3126 (0.10%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	1 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug eruption			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin discolouration			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin necrosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	4 / 3126 (0.13%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous emphysema			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Obstructive nephropathy			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	54 / 3126 (1.73%)	63 / 3127 (2.01%)	
occurrences causally related to treatment / all	10 / 64	8 / 78	
deaths causally related to treatment / all	1 / 4	0 / 3	
Calculus urinary			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	12 / 3126 (0.38%)	10 / 3127 (0.32%)	
occurrences causally related to treatment / all	0 / 12	2 / 12	
deaths causally related to treatment / all	0 / 1	1 / 2	
Cystitis glandularis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis haemorrhagic			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	4 / 3126 (0.13%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	5 / 3126 (0.16%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy toxic			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyuria			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal amyloidosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal colic			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst ruptured			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	9 / 3126 (0.29%)	11 / 3127 (0.35%)	
occurrences causally related to treatment / all	0 / 9	1 / 11	
deaths causally related to treatment / all	0 / 2	0 / 2	
Renal haemorrhage			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal impairment			
subjects affected / exposed	7 / 3126 (0.22%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 2	
Renal injury			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary fistula			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract inflammation			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prerenal failure			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Axial spondyloarthritis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	1 / 3126 (0.03%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	0 / 3126 (0.00%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility decreased			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	2 / 3126 (0.06%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	3 / 3126 (0.10%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic osteoarthropathy			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immobilisation syndrome			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	1 / 3126 (0.03%)	0 / 3127 (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	7 / 3126 (0.22%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal synovial cyst			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	9 / 3126 (0.29%)	8 / 3127 (0.26%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis of jaw			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 3126 (0.00%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			

subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oligoarthritis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis stenosans			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal sepsis			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			

subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acinetobacter sepsis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute endocarditis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	2 / 3126 (0.06%)	6 / 3127 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			
subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			

subjects affected / exposed	2 / 3126 (0.06%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial prostatitis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial pyelonephritis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	8 / 3126 (0.26%)	12 / 3127 (0.38%)	
occurrences causally related to treatment / all	0 / 8	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis viral			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bullous erysipelas			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			

subjects affected / exposed	35 / 3126 (1.12%)	22 / 3127 (0.70%)	
occurrences causally related to treatment / all	2 / 44	0 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis infective			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 3126 (0.00%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Complicated appendicitis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus infection			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus pneumonia			
subjects affected / exposed	3 / 3126 (0.10%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cystitis			
subjects affected / exposed	3 / 3126 (0.10%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis bacterial			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis escherichia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related sepsis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal perforated			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endocarditis bacterial			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis enterococcal			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Enterococcal bacteraemia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Enterococcal sepsis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Erysipelas			
subjects affected / exposed	6 / 3126 (0.19%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Escherichia bacteraemia			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			

subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	4 / 3126 (0.13%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastroenteritis			
subjects affected / exposed	7 / 3126 (0.22%)	8 / 3127 (0.26%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diverticulitis			
subjects affected / exposed	4 / 3126 (0.13%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter gastritis			

subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster disseminated			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	1 / 3126 (0.03%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Infection			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	3 / 3126 (0.10%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			

subjects affected / exposed	4 / 3126 (0.13%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal gangrene			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Kidney infection			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Large intestine infection			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			

subjects affected / exposed	1 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lymph node tuberculosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	7 / 3126 (0.22%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Osteomyelitis chronic			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreas infection			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic inflammatory disease			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis bacterial			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pyelonephritis chronic			

subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (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	113 / 3126 (3.61%)	106 / 3127 (3.39%)	
occurrences causally related to treatment / all	1 / 123	2 / 129	
deaths causally related to treatment / all	0 / 20	0 / 17	
Pneumonia aspiration			
subjects affected / exposed	7 / 3126 (0.22%)	8 / 3127 (0.26%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pneumonia bacterial			
subjects affected / exposed	3 / 3126 (0.10%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 3	
Pneumonia pseudomonal			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			

subjects affected / exposed	3 / 3126 (0.10%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic valve endocarditis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar abscess			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchitis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tuberculosis			

subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sepsis			
subjects affected / exposed	16 / 3126 (0.51%)	20 / 3127 (0.64%)	
occurrences causally related to treatment / all	0 / 17	0 / 21	
deaths causally related to treatment / all	0 / 8	0 / 12	
Septic phlebitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	17 / 3126 (0.54%)	17 / 3127 (0.54%)	
occurrences causally related to treatment / all	0 / 17	0 / 18	
deaths causally related to treatment / all	0 / 13	0 / 12	
Sinusitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	2 / 3126 (0.06%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Spontaneous bacterial peritonitis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Staphylococcal bacteraemia			

subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	2 / 3126 (0.06%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal infection			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subcutaneous abscess			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular abscess			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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			
subjects affected / exposed	1 / 3126 (0.03%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	4 / 3126 (0.13%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			

subjects affected / exposed	8 / 3126 (0.26%)	11 / 3127 (0.35%)	
occurrences causally related to treatment / all	1 / 8	2 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Viral infection			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral myositis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral pericarditis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cellulitis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	2 / 3126 (0.06%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Wound sepsis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urinary tract infection			
subjects affected / exposed	40 / 3126 (1.28%)	33 / 3127 (1.06%)	
occurrences causally related to treatment / all	4 / 49	6 / 34	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asymptomatic COVID-19			

subjects affected / exposed	24 / 3126 (0.77%)	23 / 3127 (0.74%)	
occurrences causally related to treatment / all	1 / 25	0 / 23	
deaths causally related to treatment / all	0 / 1	0 / 0	
COVID-19			
subjects affected / exposed	183 / 3126 (5.85%)	144 / 3127 (4.61%)	
occurrences causally related to treatment / all	3 / 187	0 / 147	
deaths causally related to treatment / all	0 / 23	0 / 16	
COVID-19 pneumonia			
subjects affected / exposed	86 / 3126 (2.75%)	89 / 3127 (2.85%)	
occurrences causally related to treatment / all	0 / 86	1 / 91	
deaths causally related to treatment / all	0 / 42	0 / 36	
HIV infection			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis C			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis E			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Middle East respiratory syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Suspected COVID-19			
subjects affected / exposed	17 / 3126 (0.54%)	16 / 3127 (0.51%)	
occurrences causally related to treatment / all	0 / 17	0 / 16	
deaths causally related to treatment / all	0 / 7	0 / 5	
Metabolism and nutrition disorders			
Hyperkalaemia			

subjects affected / exposed	11 / 3126 (0.35%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	2 / 12	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calciphylaxis			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Decreased appetite			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	6 / 3126 (0.19%)	8 / 3127 (0.26%)	
occurrences causally related to treatment / all	0 / 6	2 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetes mellitus inadequate control			
subjects affected / exposed	14 / 3126 (0.45%)	18 / 3127 (0.58%)	
occurrences causally related to treatment / all	0 / 17	2 / 18	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	3 / 3126 (0.10%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 4	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			

subjects affected / exposed	4 / 3126 (0.13%)	4 / 3127 (0.13%)	
occurrences causally related to treatment / all	0 / 4	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 3126 (0.00%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	6 / 3126 (0.19%)	7 / 3127 (0.22%)	
occurrences causally related to treatment / all	0 / 6	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypernatraemia			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic syndrome			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoalbuminaemia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			

subjects affected / exposed	9 / 3126 (0.29%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	1 / 9	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypokalaemia			
subjects affected / exposed	10 / 3126 (0.32%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	7 / 3126 (0.22%)	8 / 3127 (0.26%)	
occurrences causally related to treatment / all	1 / 7	2 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoproteinaemia			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	4 / 3126 (0.13%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketosis			
subjects affected / exposed	1 / 3126 (0.03%)	0 / 3127 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	1 / 3126 (0.03%)	1 / 3127 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Latent autoimmune diabetes in adults			

subjects affected / exposed	0 / 3126 (0.00%)	1 / 3127 (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 / 3126 (0.03%)	2 / 3127 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Metabolic acidosis			
subjects affected / exposed	1 / 3126 (0.03%)	5 / 3127 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypervolaemia			
subjects affected / exposed	0 / 3126 (0.00%)	3 / 3127 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3126 (0.00%)	10 / 3127 (0.32%)	
occurrences causally related to treatment / all	0 / 0	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Dapa 10 mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	464 / 3126 (14.84%)	485 / 3127 (15.51%)	
Vascular disorders			
Hypotension			
alternative assessment type: Non-systematic			
subjects affected / exposed	69 / 3126 (2.21%)	61 / 3127 (1.95%)	
occurrences (all)	80	68	
Hypertension			
alternative assessment type: Non-systematic			

subjects affected / exposed	84 / 3126 (2.69%)	102 / 3127 (3.26%)	
occurrences (all)	104	136	
Cardiac disorders			
Atrial fibrillation			
alternative assessment type: Non-systematic			
subjects affected / exposed	86 / 3126 (2.75%)	61 / 3127 (1.95%)	
occurrences (all)	103	70	
Cardiac failure			
alternative assessment type: Non-systematic			
subjects affected / exposed	179 / 3126 (5.73%)	214 / 3127 (6.84%)	
occurrences (all)	240	255	
Infections and infestations			
Urinary tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	113 / 3126 (3.61%)	112 / 3127 (3.58%)	
occurrences (all)	142	128	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 May 2018	Clinical Study Protocol Version 2.0
16 December 2019	Clinical Study Protocol Version 3.0
20 November 2020	Clinical Study Protocol Version 4.0

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported