



Clinical trial results:

A multi-center, randomized, double-blind, active-controlled, parallel-group Phase 3 study to evaluate the efficacy and safety of LCZ696 compared to ramipril on morbidity and mortality in high risk patients following an acute myocardial infarction (AMI)

Summary

EudraCT number	2016-002154-20
Trial protocol	DE PT CZ GB GR AT SK NL ES HU BE DK SE FI BG HR IT
Global end of trial date	26 February 2021

Results information

Result version number	v1 (current)
This version publication date	16 February 2022
First version publication date	16 February 2022

Trial information

Trial identification

Sponsor protocol code	CLCZ696G2301
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02924727
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, +41 613241111, Novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharmaceuticals, +41 613241111, Novartis.email@novartis.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	26 February 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that sacubitril/valsartan was superior to ramipril in delaying the time-to-first occurrence of the composite endpoint of CV death, HF hospitalization or outpatient HF in patients with LV systolic dysfunction and/or pulmonary congestion following an acute myocardial infarction (AMI)

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 251
Country: Number of subjects enrolled	Australia: 59
Country: Number of subjects enrolled	Austria: 110
Country: Number of subjects enrolled	Belgium: 80
Country: Number of subjects enrolled	Brazil: 178
Country: Number of subjects enrolled	Bulgaria: 211
Country: Number of subjects enrolled	Canada: 73
Country: Number of subjects enrolled	China: 211
Country: Number of subjects enrolled	Colombia: 134
Country: Number of subjects enrolled	Croatia: 53
Country: Number of subjects enrolled	Czechia: 152
Country: Number of subjects enrolled	Denmark: 131
Country: Number of subjects enrolled	Finland: 25
Country: Number of subjects enrolled	France: 144
Country: Number of subjects enrolled	Germany: 271
Country: Number of subjects enrolled	Greece: 66
Country: Number of subjects enrolled	Hungary: 228
Country: Number of subjects enrolled	India: 330
Country: Number of subjects enrolled	Israel: 101

Country: Number of subjects enrolled	Italy: 160
Country: Number of subjects enrolled	Korea, Republic of: 48
Country: Number of subjects enrolled	Mexico: 88
Country: Number of subjects enrolled	Netherlands: 341
Country: Number of subjects enrolled	Norway: 35
Country: Number of subjects enrolled	Peru: 28
Country: Number of subjects enrolled	Philippines: 51
Country: Number of subjects enrolled	Poland: 45
Country: Number of subjects enrolled	Portugal: 67
Country: Number of subjects enrolled	Romania: 192
Country: Number of subjects enrolled	Russian Federation: 323
Country: Number of subjects enrolled	Singapore: 87
Country: Number of subjects enrolled	Slovakia: 153
Country: Number of subjects enrolled	South Africa: 45
Country: Number of subjects enrolled	Spain: 167
Country: Number of subjects enrolled	Sweden: 76
Country: Number of subjects enrolled	Switzerland: 43
Country: Number of subjects enrolled	Taiwan: 90
Country: Number of subjects enrolled	Thailand: 80
Country: Number of subjects enrolled	Turkey: 76
Country: Number of subjects enrolled	United Kingdom: 203
Country: Number of subjects enrolled	United States: 455
Worldwide total number of subjects	5661
EEA total number of subjects	2707

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)	2837
From 65 to 84 years	2708
85 years and over	116

Subject disposition

Recruitment

Recruitment details:

A total of 5669 patients were randomized in a 1:1 ratio to the sacubitril/valsartan treatment group and the ramipril treatment group at 493 sites in 41 countries. A total of 8 patients were mis-randomized, 4 from each treatment group. The Full analysis set (FAS) was comprised of 5661 patients.

Pre-assignment

Screening details:

A total of 5669 patients were randomized in a 1:1 ratio to the sacubitril/valsartan treatment group and the ramipril treatment group at 493 sites in 41 countries. A total of 8 patients were mis-randomized, 4 from each treatment group. The Full analysis set (FAS) was comprised of 5661 patients.

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, Data analyst

Arms

Are arms mutually exclusive?	Yes
Arm title	LCZ696 (sacubitril/valsartan)

Arm description:

Following randomization, patients received LCZ696 in titrated doses from level 1 up to level 3 (50, 100 and 200 mg twice daily). Patients were required to take a total of two pills, (one tablet from the LCZ696 pack and one capsule from Ramipril matching placebo pack) twice a day for the duration of the study. Patients randomized to LCZ who were previously treated with ACE inhibitors, receiving the last dose of that agent during the last 36 hours prior to randomization, received a valsartan bridge for one day. These patients received two doses of valsartan for 1 day in a blinded manner prior to beginning double-blind LCZ696 treatment.

Arm type	Experimental
Investigational medicinal product name	LCZ696 (sacubitril/valsartan)
Investigational medicinal product code	LCZ696
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mg

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

Dosage and administration details:

Placebo to match LCZ696 50 mg, 100 mg, 200 mg

Investigational medicinal product name	LCZ696 (sacubitril/valsartan)
Investigational medicinal product code	LCZ696
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

200 mg

Investigational medicinal product name	LCZ696 (sacubitril/valsartan)
Investigational medicinal product code	LCZ696
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
100 mg	
Arm title	Ramipril

Arm description:

Following randomization, patients received Ramipril in titrated doses from level 1 up to level 3 (1.25, 2.5 and 5 mg twice daily). Patients were required to take a total of two pills, (one capsule from the Ramipril pack and one tablet from LCZ696 matching placebo pack) twice a day for the duration of the study. Patients randomized to Ramipril who were previously treated with ACE inhibitors, receiving the last dose of that agent during the last 36 hours prior to randomization immediately started on double-blind ramipril; however, to maintain double blind/double dummy of the valsartan bridge, these patients received two doses of matching valsartan placebo for 1 day in a blinded manner prior to beginning double-blind LCZ696 placebo.

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

Dosage and administration details:

1.2 mg

Investigational medicinal product name	Ramipril
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2.5 mg

Investigational medicinal product name	Ramipril
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

5 mg

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo to match Ramipril 1.25 mg, 2.5 mg, 5 mg

Number of subjects in period 1	LCZ696 (sacubitril/valsartan)	Ramipril
Started	2830	2831
Completed	2605	2576
Not completed	225	255
Adverse event, serious fatal	221	246
Consent withdrawn by subject	2	4
Lost to follow-up	2	5

Baseline characteristics

Reporting groups

Reporting group title	LCZ696 (sacubitril/valsartan)
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Reporting group description:

Following randomization, patients received LCZ696 in titrated doses from level 1 up to level 3 (50, 100 and 200 mg twice daily). Patients were required to take a total of two pills, (one tablet from the LCZ696 pack and one capsule from Ramipril matching placebo pack) twice a day for the duration of the study. Patients randomized to LCZ who were previously treated with ACE inhibitors, receiving the last dose of that agent during the last 36 hours prior to randomization, received a valsartan bridge for one day. These patients received two doses of valsartan for 1 day in a blinded manner prior to beginning double-blind LCZ696 treatment.

Reporting group title	Ramipril
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Reporting group description:

Following randomization, patients received Ramipril in titrated doses from level 1 up to level 3 (1.25, 2.5 and 5 mg twice daily). Patients were required to take a total of two pills, (one capsule from the Ramipril pack and one tablet from LCZ696 matching placebo pack) twice a day for the duration of the study. Patients randomized to Ramipril who were previously treated with ACE inhibitors, receiving the last dose of that agent during the last 36 hours prior to randomization immediately started on double-blind ramipril; however, to maintain double blind/double dummy of the valsartan bridge, these patients received two doses of matching valsartan placebo for 1 day in a blinded manner prior to beginning double-blind LCZ696 placebo.

Reporting group values	LCZ696 (sacubitril/valsartan)	Ramipril	Total
Number of subjects	2830	2831	5661
Age Categorical			
Age Customized			
Units: Participants			
18 years to <65 years	1386	1451	2837
≥65 years to ≥85	1377	1331	2708
>85 years	67	49	116
Age continuous			
Units: years			
arithmetic mean	64.0	63.5	
standard deviation	± 11.63	± 11.36	-
Sex: Female, Male			
Units: Participants			
Female	663	700	1363
Male	2167	2131	4298
Race/Ethnicity, Customized			
Race/Ethnicity			
Units: Subjects			
Caucasian	2125	2138	4263
Black	35	40	75
Asian	475	478	953
Native American	45	45	90
Pacific Islander	0	4	4
Unknown	22	21	43
Other	128	105	233

End points

End points reporting groups

Reporting group title	LCZ696 (sacubitril/valsartan)
Reporting group description: Following randomization, patients received LCZ696 in titrated doses from level 1 up to level 3 (50, 100 and 200 mg twice daily). Patients were required to take a total of two pills, (one tablet from the LCZ696 pack and one capsule from Ramipril matching placebo pack) twice a day for the duration of the study. Patients randomized to LCZ who were previously treated with ACE inhibitors, receiving the last dose of that agent during the last 36 hours prior to randomization, received a valsartan bridge for one day. These patients received two doses of valsartan for 1 day in a blinded manner prior to beginning double-blind LCZ696 treatment.	
Reporting group title	Ramipril
Reporting group description: Following randomization, patients received Ramipril in titrated doses from level 1 up to level 3 (1.25, 2.5 and 5 mg twice daily). Patients were required to take a total of two pills, (one capsule from the Ramipril pack and one tablet from LCZ696 matching placebo pack) twice a day for the duration of the study. Patients randomized to Ramipril who were previously treated with ACE inhibitors, receiving the last dose of that agent during the last 36 hours prior to randomization immediately started on double-blind ramipril; however, to maintain double blind/double dummy of the valsartan bridge, these patients received two doses of matching valsartan placebo for 1 day in a blinded manner prior to beginning double-blind LCZ696 placebo.	

Primary: Number of Participants with first CEC (clinical endpoint committee) confirmed primary composite endpoint

End point title	Number of Participants with first CEC (clinical endpoint committee) confirmed primary composite endpoint
End point description: A confirmed composite endpoint includes cardiovascular (CV) death, heart failure (HF) hospitalization, or outpatient heart failure	
End point type	Primary
End point timeframe: From randomization to first occurrence (up to approximately 43 months)	

End point values	LCZ696 (sacubitril/valsartan)	Ramipril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2830	2831		
Units: Count of Participants				
Primary Composite	338	373		
Cardiovascular (CV) Death	168	191		
First Heart Failure (HF) Hospitalization	170	195		
First Outpatient Heart Failure (HF)	39	57		

Statistical analyses

Statistical analysis title	LCZ696 vs Ramipril
Statistical analysis description:	
Primary Composite	
Comparison groups	LCZ696 (sacubitril/valsartan) v Ramipril
Number of subjects included in analysis	5661
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1659
Method	Cox's Proportional Hazard Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9012
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7778
upper limit	1.0441

Statistical analysis title	LCZ696 vs Ramipril
Statistical analysis description:	
CV Death	
Comparison groups	LCZ696 (sacubitril/valsartan) v Ramipril
Number of subjects included in analysis	5661
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2031
Method	Cox's Proportional Hazard Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.874
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7104
upper limit	1.0754

Statistical analysis title	LCZ696 vs Ramipril
Statistical analysis description:	
First HF Hospitalization	
Comparison groups	LCZ696 (sacubitril/valsartan) v Ramipril
Number of subjects included in analysis	5661
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1679
Method	Cox's Proportional Hazard Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8653

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7044
upper limit	1.0629

Statistical analysis title	LCZ696 vs Ramipril
Statistical analysis description:	
First Outpatient HF	
Comparison groups	LCZ696 (sacubitril/valsartan) v Ramipril
Number of subjects included in analysis	5661
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0667
Method	Cox's Proportional Hazard Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.6831
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4546
upper limit	1.0266

Secondary: Number of participants with a confirmed composite of CV death or HF hospitalization

End point title	Number of participants with a confirmed composite of CV death or HF hospitalization
End point description:	
A confirmed composite endpoint for this outcome measure includes cardiovascular death or heart failure hospitalization.	
End point type	Secondary
End point timeframe:	
Time from randomization to first occurrence (up to approximately 43 months)	

End point values	LCZ696 (sacubitril/valsartan)	Ramipril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2830	2831		
Units: Participants	308	335		

Statistical analyses

Statistical analysis title	LCZ696 vs Ramipril
Statistical analysis description: CV death or HF hospitalization	
Comparison groups	LCZ696 (sacubitril/valsartan) v Ramipril
Number of subjects included in analysis	5661
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2507
Method	Cox's Proportional Hazard Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9133
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7824
upper limit	1.0662

Secondary: Number of Participants with a confirmed composite of HF hospitalization or outpatient HF

End point title	Number of Participants with a confirmed composite of HF hospitalization or outpatient HF
End point description: A confirmed composite endpoint includes first occurrence of heart failure hospitalization or outpatient heart failure	
End point type	Secondary
End point timeframe: Time from randomization to first occurrence (approximately up to 43 months)	

End point values	LCZ696 (sacubitril/valsartan)	Ramipril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2830	2831		
Units: Participants	201	237		

Statistical analyses

Statistical analysis title	LCZ696 vs Ramipril
Statistical analysis description: HF hospitalization or Outpatient HF	
Comparison groups	LCZ696 (sacubitril/valsartan) v Ramipril

Number of subjects included in analysis	5661
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0732
Method	Cox's Proportional Hazard Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8422
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6979
upper limit	1.0163

Secondary: Number of Participants with a confirmed composite of CV death, non-fatal spontaneous myocardial infarction or non-fatal stroke

End point title	Number of Participants with a confirmed composite of CV death, non-fatal spontaneous myocardial infarction or non-fatal stroke
End point description:	A confirmed composite endpoint for this outcome measure includes cardiovascular death, non-fatal spontaneous myocardial infarction or non-fatal stroke
End point type	Secondary
End point timeframe:	Time from randomization to first occurrence (approximately up to 43 months)

End point values	LCZ696 (sacubitril/valsartan)	Ramipril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2830	2831		
Units: Participants	315	349		

Statistical analyses

Statistical analysis title	LCZ696 vs Ramipril
Statistical analysis description:	CV death, Non-fatal spontaneous MI or Non-fatal stroke
Comparison groups	LCZ696 (sacubitril/valsartan) v Ramipril
Number of subjects included in analysis	5661
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1785
Method	Cox's Proportional Hazard Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9007

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7734
upper limit	1.0489

Secondary: Total Number of Confirmed Composite Endpoints

End point title	Total Number of Confirmed Composite Endpoints
End point description:	
A confirmed composite endpoint includes cardiovascular death, heart failure hospitalization, non-fatal spontaneous MI hospitalization, and non-fatal stroke hospitalization	
End point type	Secondary
End point timeframe:	
Time from randomization to end of study (approximately up to 43 months)	

End point values	LCZ696 (sacubitril/valsartan)	Ramipril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2830	2831		
Units: Events	416	455		

Statistical analyses

Statistical analysis title	LCZ696 vs Ramipril
Statistical analysis description:	
Total Number of Confirmed Composite Endpoints	
Comparison groups	LCZ696 (sacubitril/valsartan) v Ramipril
Number of subjects included in analysis	5661
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0452
Method	Negative Binomial regression model
Parameter estimate	Rate Ratio
Point estimate	0.8361
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7018
upper limit	0.9961

Secondary: All-cause mortality for Full Analysis Set (FAS)

End point title	All-cause mortality for Full Analysis Set (FAS)
End point description: All-cause mortality defined as deaths related to Cardiovascular (CV) and non-CV events for patients in the Full Analysis Set	
End point type	Secondary
End point timeframe: Time from randomization to death (approximately up to 43 months)	

End point values	LCZ696 (sacubitril/valsartan)	Ramipril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2830	2831		
Units: Participants	213	242		

Statistical analyses

Statistical analysis title	LCZ696 vs Ramipril
Statistical analysis description: All-Cause Death	
Comparison groups	LCZ696 (sacubitril/valsartan) v Ramipril
Number of subjects included in analysis	5661
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1556
Method	Cox's Proportional Hazard Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8751
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7279
upper limit	1.052

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from first dose of study treatment until end of study treatment plus 30 days post treatment, up to maximum duration of approximately 4 years.

Adverse event reporting additional description:

Any sign or symptom that occurs during the study treatment plus the 30 days post treatment.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	Ramipril
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Reporting group description:

Ramipril

Reporting group title	LCZ696
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Reporting group description:

LCZ696

Serious adverse events	Ramipril	LCZ696	
Total subjects affected by serious adverse events			
subjects affected / exposed	1126 / 2816 (39.99%)	1146 / 2820 (40.64%)	
number of deaths (all causes)	244	220	
number of deaths resulting from adverse events	5	4	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Anaplastic meningioma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
B-cell small lymphocytic lymphoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell unclassifiable lymphoma low grade			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	3 / 2816 (0.11%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign duodenal neoplasm			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder cancer			
subjects affected / exposed	0 / 2816 (0.00%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder transitional cell carcinoma			

subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	1 / 2816 (0.04%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage II			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			

subjects affected / exposed	5 / 2816 (0.18%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	1 / 2816 (0.04%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colorectal adenocarcinoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder adenosquamous carcinoma			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gallbladder cancer			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			

subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric neoplasm			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal carcinoma			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatocellular carcinoma			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hepatic cancer			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Haemangioma of liver			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypopharyngeal cancer			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected neoplasm			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratoacanthoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Lung neoplasm			

subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lung neoplasm malignant			
subjects affected / exposed	5 / 2816 (0.18%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 1	
Lung squamous cell carcinoma metastatic			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant melanoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant peritoneal neoplasm			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant neoplasm of pleura			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Marginal zone lymphoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			

subjects affected / exposed	3 / 2816 (0.11%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to lymph nodes			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastasis			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Metastatic neoplasm			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myeloproliferative neoplasm			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Monoclonal gammopathy			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myxoid liposarcoma			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm progression			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neuroendocrine carcinoma			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	0 / 2816 (0.00%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oropharyngeal cancer			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	0 / 2816 (0.00%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
Papillary cystadenoma lymphomatosum			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural mesothelioma malignant			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	3 / 2816 (0.11%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal adenocarcinoma			
subjects affected / exposed	1 / 2816 (0.04%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	1 / 2816 (0.04%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal neoplasm			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer metastatic			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			

subjects affected / exposed	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular neoplasm			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the parotid gland			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour haemorrhage			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vulval cancer			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Aneurysm ruptured			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiodysplasia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	3 / 2816 (0.11%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic stenosis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic occlusion			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial haemorrhage			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial occlusive disease			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stenosis			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial thrombosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	3 / 2816 (0.11%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachiocephalic arteriosclerosis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Distributive shock			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism arterial			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			

subjects affected / exposed	1 / 2816 (0.04%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery aneurysm			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	7 / 2816 (0.25%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	9 / 2816 (0.32%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	3 / 2816 (0.11%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
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	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	15 / 2816 (0.53%)	37 / 2820 (1.31%)	
occurrences causally related to treatment / all	7 / 16	23 / 42	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hypovolaemic shock			

subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery stenosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery occlusion			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			
subjects affected / exposed	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic limb pain			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive shock			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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 / 2816 (0.11%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	2 / 3	3 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			

subjects affected / exposed	9 / 2816 (0.32%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	0 / 2816 (0.00%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	0 / 2816 (0.00%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 2816 (0.04%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	1 / 2816 (0.04%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	9 / 2816 (0.32%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reperfusion injury			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery occlusion			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous aneurysm			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous haemorrhage			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Cardiac pacemaker insertion			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transcatheter aortic valve implantation			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			

Hyperemesis gravidarum			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pre-eclampsia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse event			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	4 / 2816 (0.14%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 5	
Chest discomfort			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	3 / 2816 (0.11%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	31 / 2816 (1.10%)	27 / 2820 (0.96%)	
occurrences causally related to treatment / all	0 / 31	2 / 27	
deaths causally related to treatment / all	0 / 31	2 / 27	
Chest pain			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

Complication associated with device			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drowning			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
General physical health deterioration			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Exercise tolerance decreased			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised oedema			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	3 / 2816 (0.11%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
Necrosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	66 / 2816 (2.34%)	54 / 2820 (1.91%)	
occurrences causally related to treatment / all	0 / 70	0 / 64	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	3 / 2816 (0.11%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sudden cardiac death			

subjects affected / exposed	14 / 2816 (0.50%)	10 / 2820 (0.35%)	
occurrences causally related to treatment / all	0 / 14	0 / 10	
deaths causally related to treatment / all	0 / 14	0 / 10	
Sudden death			
subjects affected / exposed	8 / 2816 (0.28%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 8	0 / 9	
Surgical failure			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer haemorrhage			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unevaluable event			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	5 / 2816 (0.18%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	7 / 2816 (0.25%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 2	
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast media allergy			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Immobile			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Imprisonment			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 2816 (0.04%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast necrosis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast pain			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cervical polyp			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysterocele			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal oedema			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine haemorrhage			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	13 / 2816 (0.46%)	19 / 2820 (0.67%)	
occurrences causally related to treatment / all	0 / 17	0 / 24	
deaths causally related to treatment / all	0 / 1	0 / 3	
Acute respiratory failure			
subjects affected / exposed	5 / 2816 (0.18%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 3	0 / 3	
Aspiration			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthma			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	13 / 2816 (0.46%)	14 / 2820 (0.50%)	
occurrences causally related to treatment / all	0 / 23	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	28 / 2816 (0.99%)	34 / 2820 (1.21%)	
occurrences causally related to treatment / all	6 / 34	0 / 38	
deaths causally related to treatment / all	0 / 3	0 / 0	
Cough			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea at rest			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	2 / 2816 (0.07%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epistaxis			
subjects affected / exposed	7 / 2816 (0.25%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	4 / 2816 (0.14%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Haemothorax			

subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	1 / 2816 (0.04%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	3 / 2816 (0.11%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung consolidation			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	6 / 2816 (0.21%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Painful respiration			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthopnoea			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary alveolar haemorrhage			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary artery thrombosis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	3 / 2816 (0.11%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary embolism			
subjects affected / exposed	5 / 2816 (0.18%)	8 / 2820 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			

subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	13 / 2816 (0.46%)	12 / 2820 (0.43%)	
occurrences causally related to treatment / all	0 / 17	0 / 12	
deaths causally related to treatment / all	0 / 2	0 / 2	
Pulmonary pain			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal stenosis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	11 / 2816 (0.39%)	11 / 2820 (0.39%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 2	0 / 1	
Psychiatric disorders			
Anxiety			

subjects affected / exposed	5 / 2816 (0.18%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Confusional state			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delusion			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Depression suicidal			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional self-injury			

subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Personality change due to a general medical condition			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric decompensation			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restlessness			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device breakage			

subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (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 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device defective			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device fastener issue			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lead dislodgement			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary cyst			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Biliary dilatation			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dyspepsia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	6 / 2816 (0.21%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	9 / 2816 (0.32%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 10	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	1 / 2816 (0.04%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hepatic mass			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic pain			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Angiocardiogram			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy bladder			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy prostate			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Blood glucose increased			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose fluctuation			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac output decreased			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Blood sodium decreased			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ventriculogram			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulation test abnormal			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction			

subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction abnormal			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	12 / 2816 (0.43%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 12	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glycosylated haemoglobin increased			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate decreased			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza B virus test positive			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Occult blood positive			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal function test abnormal			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 test positive			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Scan myocardial perfusion abnormal			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress echocardiogram			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight increased			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental exposure to product			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic leak			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial bypass occlusion			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial injury			
subjects affected / exposed	1 / 2816 (0.04%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac function disturbance postoperative			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac procedure complication			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve rupture			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	5 / 2816 (0.18%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	3 / 2816 (0.11%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary bypass thrombosis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary vascular graft occlusion			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			

subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electric shock			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Fall			
subjects affected / exposed	7 / 2816 (0.25%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 7	2 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Femur fracture			
subjects affected / exposed	4 / 2816 (0.14%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body in gastrointestinal tract			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture displacement			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	3 / 2816 (0.11%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			

subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	3 / 2816 (0.11%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle injury			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital haemorrhage			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax traumatic			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprocedural myocardial infarction			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Post intensive care syndrome			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural discharge			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fistula			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	2 / 2816 (0.07%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural myocardial infarction			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural urine leak			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prevertebral soft tissue swelling of cervical space			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary contusion			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			

subjects affected / exposed	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin abrasion			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomal hernia			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous haematoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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 / 2816 (0.14%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Toxicity to various agents			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	3 / 2816 (0.11%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasoplegia syndrome			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Ventricular septal defect			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	13 / 2816 (0.46%)	11 / 2820 (0.39%)	
occurrences causally related to treatment / all	1 / 14	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	6 / 2816 (0.21%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	1 / 6	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 1	

Acute myocardial infarction			
subjects affected / exposed	95 / 2816 (3.37%)	92 / 2820 (3.26%)	
occurrences causally related to treatment / all	0 / 101	1 / 100	
deaths causally related to treatment / all	0 / 13	0 / 8	
Adams-Stokes syndrome			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	84 / 2816 (2.98%)	59 / 2820 (2.09%)	
occurrences causally related to treatment / all	0 / 91	0 / 69	
deaths causally related to treatment / all	0 / 4	0 / 2	
Angina unstable			
subjects affected / exposed	76 / 2816 (2.70%)	65 / 2820 (2.30%)	
occurrences causally related to treatment / all	0 / 89	0 / 70	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anginal equivalent			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			

subjects affected / exposed	3 / 2816 (0.11%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	0 / 3	0 / 10	
deaths causally related to treatment / all	0 / 3	0 / 6	
Arteriosclerosis coronary artery			
subjects affected / exposed	5 / 2816 (0.18%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrial fibrillation			
subjects affected / exposed	22 / 2816 (0.78%)	30 / 2820 (1.06%)	
occurrences causally related to treatment / all	0 / 26	0 / 32	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrial flutter			
subjects affected / exposed	7 / 2816 (0.25%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	1 / 2816 (0.04%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	4 / 2816 (0.14%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			

subjects affected / exposed	4 / 2816 (0.14%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac aneurysm			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac arrest			
subjects affected / exposed	31 / 2816 (1.10%)	24 / 2820 (0.85%)	
occurrences causally related to treatment / all	0 / 32	0 / 27	
deaths causally related to treatment / all	0 / 18	0 / 13	
Cardiac asthma			
subjects affected / exposed	3 / 2816 (0.11%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac discomfort			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	183 / 2816 (6.50%)	149 / 2820 (5.28%)	
occurrences causally related to treatment / all	4 / 249	4 / 219	
deaths causally related to treatment / all	1 / 18	0 / 18	
Cardiac failure acute			
subjects affected / exposed	22 / 2816 (0.78%)	28 / 2820 (0.99%)	
occurrences causally related to treatment / all	1 / 33	0 / 33	
deaths causally related to treatment / all	0 / 4	0 / 3	
Cardiac failure chronic			

subjects affected / exposed	8 / 2816 (0.28%)	12 / 2820 (0.43%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	37 / 2816 (1.31%)	27 / 2820 (0.96%)	
occurrences causally related to treatment / all	2 / 54	0 / 33	
deaths causally related to treatment / all	1 / 7	0 / 3	
Cardiac perforation			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	6 / 2816 (0.21%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Cardiac ventricular thrombosis			
subjects affected / exposed	8 / 2816 (0.28%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	1 / 2816 (0.04%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 5	
Cardiogenic shock			
subjects affected / exposed	12 / 2816 (0.43%)	17 / 2820 (0.60%)	
occurrences causally related to treatment / all	1 / 12	0 / 18	
deaths causally related to treatment / all	1 / 11	0 / 6	
Cardiomyopathy			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiovascular insufficiency			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic left ventricular failure			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery insufficiency			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery disease			
subjects affected / exposed	30 / 2816 (1.07%)	23 / 2820 (0.82%)	
occurrences causally related to treatment / all	0 / 30	0 / 24	
deaths causally related to treatment / all	0 / 1	0 / 1	
Coronary artery occlusion			
subjects affected / exposed	6 / 2816 (0.21%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery perforation			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	4 / 2816 (0.14%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dressler's syndrome			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis noninfective			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac thrombus			
subjects affected / exposed	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	10 / 2816 (0.36%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	3 / 2816 (0.11%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Left ventricular failure			
subjects affected / exposed	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Microvascular coronary artery disease			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	4 / 2816 (0.14%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocardial infarction			
subjects affected / exposed	44 / 2816 (1.56%)	51 / 2820 (1.81%)	
occurrences causally related to treatment / all	1 / 47	0 / 51	
deaths causally related to treatment / all	0 / 9	0 / 18	
Myocardial ischaemia			
subjects affected / exposed	9 / 2816 (0.32%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 4	0 / 1	
Palpitations			
subjects affected / exposed	1 / 2816 (0.04%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary muscle disorder			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paroxysmal atrioventricular block			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	6 / 2816 (0.21%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial haemorrhage			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	8 / 2816 (0.28%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sinus bradycardia			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	3 / 2816 (0.11%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	3 / 2816 (0.11%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricle rupture			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tachycardia			

subjects affected / exposed	1 / 2816 (0.04%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	5 / 2816 (0.18%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ventricular dysfunction			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	11 / 2816 (0.39%)	12 / 2820 (0.43%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 4	0 / 5	
Ventricular remodelling			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	23 / 2816 (0.82%)	19 / 2820 (0.67%)	
occurrences causally related to treatment / all	0 / 26	0 / 19	
deaths causally related to treatment / all	0 / 2	0 / 0	
Nervous system disorders			
Arachnoid cyst			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem ischaemia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	2 / 2816 (0.07%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	9 / 2816 (0.32%)	8 / 2820 (0.28%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cerebral hypoperfusion			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral venous sinus thrombosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	33 / 2816 (1.17%)	32 / 2820 (1.13%)	
occurrences causally related to treatment / all	0 / 38	0 / 36	
deaths causally related to treatment / all	0 / 3	0 / 5	
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular disorder			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disturbance in attention			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Demyelinating polyneuropathy			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dizziness			
subjects affected / exposed	3 / 2816 (0.11%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	1 / 3	3 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness postural			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
Haemorrhagic transformation stroke			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hemianopia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			

subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Irregular sleep wake rhythm disorder			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ischaemic stroke			
subjects affected / exposed	15 / 2816 (0.53%)	12 / 2820 (0.43%)	
occurrences causally related to treatment / all	0 / 15	1 / 12	
deaths causally related to treatment / all	0 / 4	0 / 0	
Lacunar stroke			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar infarction			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			

subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Moyamoya disease			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post stroke seizure			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	4 / 2816 (0.14%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	0 / 4	2 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychogenic seizure			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	6 / 2816 (0.21%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Spinal cord haemorrhage			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subdural hygroma			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	30 / 2816 (1.07%)	36 / 2820 (1.28%)	
occurrences causally related to treatment / all	4 / 31	9 / 43	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transient ischaemic attack			
subjects affected / exposed	10 / 2816 (0.36%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	0 / 11	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia macrocytic			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	23 / 2816 (0.82%)	30 / 2820 (1.06%)	
occurrences causally related to treatment / all	0 / 25	0 / 31	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood loss anaemia			
subjects affected / exposed	1 / 2816 (0.04%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilia			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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 / 2816 (0.04%)	2 / 2820 (0.07%)	
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	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	4 / 2816 (0.14%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			

subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Splenic haemorrhage			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	5 / 2816 (0.18%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

Arteriosclerotic retinopathy			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye oedema			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye swelling			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iridocyclitis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular haematoma			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open angle glaucoma			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital oedema			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhegmatogenous retinal detachment			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			

subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal mass			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	5 / 2816 (0.18%)	8 / 2820 (0.28%)	
occurrences causally related to treatment / all	1 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal pain upper			
subjects affected / exposed	5 / 2816 (0.18%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	1 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ascites			

subjects affected / exposed	4 / 2816 (0.14%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute abdomen			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colitis ischaemic			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental cyst			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	8 / 2816 (0.28%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			

subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faeces discoloured			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	5 / 2816 (0.18%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal haemorrhage			
subjects affected / exposed	12 / 2816 (0.43%)	15 / 2820 (0.53%)	
occurrences causally related to treatment / all	0 / 12	0 / 16	
deaths causally related to treatment / all	0 / 2	0 / 1	
Gastrointestinal disorder			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 2816 (0.07%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids thrombosed			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	2 / 2816 (0.07%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	3 / 2816 (0.11%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal pseudo-obstruction			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip swelling			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical ileus			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malabsorption			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Melaena			

subjects affected / exposed	1 / 2816 (0.04%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth swelling			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric arterial occlusion			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nausea			
subjects affected / exposed	1 / 2816 (0.04%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	5 / 2816 (0.18%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatitis			
subjects affected / exposed	3 / 2816 (0.11%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal achalasia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal adhesions			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			

subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	6 / 2816 (0.21%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 2816 (0.11%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	5 / 2816 (0.18%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	5 / 2816 (0.18%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	5 / 5	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	3 / 2816 (0.11%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic wound			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperhidrosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash maculo-papular			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Symmetrical drug-related intertriginous and flexural exanthema			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	0 / 2816 (0.00%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	30 / 2816 (1.07%)	37 / 2820 (1.31%)	
occurrences causally related to treatment / all	12 / 36	12 / 40	
deaths causally related to treatment / all	0 / 0	2 / 3	
Anuria			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Azotaemia			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder tamponade			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	1 / 2816 (0.04%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 1	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	7 / 2816 (0.25%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage urinary tract			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			

subjects affected / exposed	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	8 / 2816 (0.28%)	10 / 2820 (0.35%)	
occurrences causally related to treatment / all	2 / 8	2 / 11	
deaths causally related to treatment / all	0 / 1	0 / 4	
Renal haematoma			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	6 / 2816 (0.21%)	14 / 2820 (0.50%)	
occurrences causally related to treatment / all	3 / 6	7 / 15	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ureteric obstruction			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral obstruction			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	1 / 2816 (0.04%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal mass			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Arthritis reactive			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	0 / 2816 (0.00%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back disorder			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	3 / 2816 (0.11%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deformity thorax			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enthesopathy			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula discharge			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			

subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility decreased			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	5 / 2816 (0.18%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	6 / 2816 (0.21%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periostosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudarthrosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			

subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess jaw			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess oral			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	3 / 2816 (0.11%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			

subjects affected / exposed	1 / 2816 (0.04%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial abdominal infection			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	6 / 2816 (0.21%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone abscess			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	16 / 2816 (0.57%)	13 / 2820 (0.46%)	
occurrences causally related to treatment / all	0 / 16	0 / 13	
deaths causally related to treatment / all	0 / 4	0 / 5	
COVID-19 pneumonia			

subjects affected / exposed	8 / 2816 (0.28%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 4	0 / 2	
Carbuncle			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	5 / 2816 (0.18%)	11 / 2820 (0.39%)	
occurrences causally related to treatment / all	0 / 5	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis infective			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus infection			
subjects affected / exposed	3 / 2816 (0.11%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cystitis			
subjects affected / exposed	2 / 2816 (0.07%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			

subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endocarditis			
subjects affected / exposed	0 / 2816 (0.00%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Empyema			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometritis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis staphylococcal			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			

subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	5 / 2816 (0.18%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fournier's gangrene			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gangrene			
subjects affected / exposed	5 / 2816 (0.18%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gas gangrene			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			

subjects affected / exposed	7 / 2816 (0.25%)	11 / 2820 (0.39%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital herpes			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter duodenal ulcer			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site abscess			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected dermal cyst			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	3 / 2816 (0.11%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint abscess			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labyrinthitis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			

subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	2 / 2816 (0.07%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis bacterial			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	1 / 2816 (0.04%)	4 / 2820 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Orchitis			

subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pharyngeal abscess			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngotonsillitis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (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	73 / 2816 (2.59%)	61 / 2820 (2.16%)	
occurrences causally related to treatment / all	0 / 79	0 / 65	
deaths causally related to treatment / all	0 / 8	0 / 7	
Pneumonia bacterial			
subjects affected / exposed	0 / 2816 (0.00%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Postoperative wound infection			
subjects affected / exposed	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural sepsis			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pyelonephritis			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 2816 (0.04%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
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	6 / 2816 (0.21%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	1 / 7	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Respiratory tract infection viral			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinovirus infection			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal abscess			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	13 / 2816 (0.46%)	19 / 2820 (0.67%)	
occurrences causally related to treatment / all	0 / 13	0 / 24	
deaths causally related to treatment / all	0 / 7	0 / 7	
Septic shock			
subjects affected / exposed	8 / 2816 (0.28%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 4	0 / 4	
Skin infection			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected COVID-19			
subjects affected / exposed	0 / 2816 (0.00%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	16 / 2816 (0.57%)	28 / 2820 (0.99%)	
occurrences causally related to treatment / all	0 / 17	0 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			

subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	2 / 2816 (0.07%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral labyrinthitis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral sepsis			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound abscess			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	3 / 2816 (0.11%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection bacterial			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis hyperchloraemic			

subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	10 / 2816 (0.36%)	9 / 2820 (0.32%)	
occurrences causally related to treatment / all	0 / 10	1 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cachexia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetes mellitus inadequate control			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	2 / 2816 (0.07%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic metabolic decompensation			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	3 / 2816 (0.11%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Euglycaemic diabetic ketoacidosis			

subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid overload			
subjects affected / exposed	2 / 2816 (0.07%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	2 / 2816 (0.07%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food intolerance			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	4 / 2816 (0.14%)	15 / 2820 (0.53%)	
occurrences causally related to treatment / all	2 / 4	12 / 20	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			

subjects affected / exposed	4 / 2816 (0.14%)	6 / 2820 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	3 / 2816 (0.11%)	5 / 2820 (0.18%)	
occurrences causally related to treatment / all	1 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	10 / 2816 (0.36%)	7 / 2820 (0.25%)	
occurrences causally related to treatment / all	1 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	4 / 2816 (0.14%)	3 / 2820 (0.11%)	
occurrences causally related to treatment / all	1 / 4	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophosphataemia			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	1 / 2816 (0.04%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			

subjects affected / exposed	2 / 2816 (0.07%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudohyponatraemia			
subjects affected / exposed	0 / 2816 (0.00%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	4 / 2816 (0.14%)	0 / 2820 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	1 / 2816 (0.04%)	1 / 2820 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	1 / 2816 (0.04%)	2 / 2820 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Ramipril	LCZ696	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1770 / 2816 (62.86%)	1769 / 2820 (62.73%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	288 / 2816 (10.23%)	447 / 2820 (15.85%)	
occurrences (all)	339	537	
Hypertension			

subjects affected / exposed occurrences (all)	143 / 2816 (5.08%) 158	96 / 2820 (3.40%) 105	
Orthostatic hypotension subjects affected / exposed occurrences (all)	32 / 2816 (1.14%) 34	66 / 2820 (2.34%) 69	
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	136 / 2816 (4.83%) 147	125 / 2820 (4.43%) 131	
Asthenia subjects affected / exposed occurrences (all)	58 / 2816 (2.06%) 67	67 / 2820 (2.38%) 69	
Non-cardiac chest pain subjects affected / exposed occurrences (all)	156 / 2816 (5.54%) 187	183 / 2820 (6.49%) 222	
Oedema peripheral subjects affected / exposed occurrences (all)	125 / 2816 (4.44%) 150	122 / 2820 (4.33%) 140	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	359 / 2816 (12.75%) 398	239 / 2820 (8.48%) 278	
Dyspnoea subjects affected / exposed occurrences (all)	251 / 2816 (8.91%) 285	185 / 2820 (6.56%) 216	
Dyspnoea exertional subjects affected / exposed occurrences (all)	51 / 2816 (1.81%) 55	63 / 2820 (2.23%) 71	
Epistaxis subjects affected / exposed occurrences (all)	79 / 2816 (2.81%) 91	60 / 2820 (2.13%) 69	
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	74 / 2816 (2.63%) 78	53 / 2820 (1.88%) 54	

Investigations Blood creatinine increased subjects affected / exposed occurrences (all)	58 / 2816 (2.06%) 67	51 / 2820 (1.81%) 59	
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all) Angina pectoris subjects affected / exposed occurrences (all) Cardiac failure subjects affected / exposed occurrences (all)	87 / 2816 (3.09%) 99 140 / 2816 (4.97%) 162 150 / 2816 (5.33%) 177	85 / 2820 (3.01%) 92 125 / 2820 (4.43%) 146 128 / 2820 (4.54%) 143	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Syncope subjects affected / exposed occurrences (all)	241 / 2816 (8.56%) 273 69 / 2816 (2.45%) 74 57 / 2816 (2.02%) 60	280 / 2820 (9.93%) 334 78 / 2820 (2.77%) 86 52 / 2820 (1.84%) 56	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	123 / 2816 (4.37%) 125	130 / 2820 (4.61%) 136	
Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all) Diarrhoea	57 / 2816 (2.02%) 60 99 / 2816 (3.52%) 104	42 / 2820 (1.49%) 43 70 / 2820 (2.48%) 76	

subjects affected / exposed	179 / 2816 (6.36%)	227 / 2820 (8.05%)	
occurrences (all)	204	253	
Nausea			
subjects affected / exposed	101 / 2816 (3.59%)	93 / 2820 (3.30%)	
occurrences (all)	109	99	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	59 / 2816 (2.10%)	72 / 2820 (2.55%)	
occurrences (all)	64	80	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	50 / 2816 (1.78%)	58 / 2820 (2.06%)	
occurrences (all)	54	62	
Renal impairment			
subjects affected / exposed	129 / 2816 (4.58%)	124 / 2820 (4.40%)	
occurrences (all)	142	144	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	103 / 2816 (3.66%)	114 / 2820 (4.04%)	
occurrences (all)	120	125	
Back pain			
subjects affected / exposed	103 / 2816 (3.66%)	72 / 2820 (2.55%)	
occurrences (all)	110	72	
Myalgia			
subjects affected / exposed	80 / 2816 (2.84%)	70 / 2820 (2.48%)	
occurrences (all)	86	76	
Pain in extremity			
subjects affected / exposed	95 / 2816 (3.37%)	88 / 2820 (3.12%)	
occurrences (all)	103	97	
Infections and infestations			
Pneumonia			
subjects affected / exposed	66 / 2816 (2.34%)	58 / 2820 (2.06%)	
occurrences (all)	71	63	
Nasopharyngitis			
subjects affected / exposed	72 / 2816 (2.56%)	107 / 2820 (3.79%)	
occurrences (all)	88	130	

Upper respiratory tract infection subjects affected / exposed occurrences (all)	57 / 2816 (2.02%) 61	54 / 2820 (1.91%) 61	
Urinary tract infection subjects affected / exposed occurrences (all)	95 / 2816 (3.37%) 106	97 / 2820 (3.44%) 114	
Metabolism and nutrition disorders			
Hyperkalaemia subjects affected / exposed occurrences (all)	249 / 2816 (8.84%) 331	256 / 2820 (9.08%) 348	
Hypokalaemia subjects affected / exposed occurrences (all)	56 / 2816 (1.99%) 61	76 / 2820 (2.70%) 84	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 June 2016	The purpose of this amendment was to refine the recommendations for alternative treatment to ensure sufficient renin angiotensin system (RAS) blockade in the event a patient needs to discontinue the study drug due to intolerable adverse events.
25 April 2017	The purpose of this amendment was to add an echocardiographic substudy to the protocol. The amendment also removed the targeted adverse event data collection, and provided additional guidance for co-administering LCZ696 with atorvastatin or other statins.
01 May 2019	The purpose of this amendment was to increase the sample size from 4,650 to 5,650 and adjust the assumption for the primary composite endpoint events of cardiovascular (CV) death, heart failure (HF) hospitalization, or outpatient HF treatment effect from 18% to 19%.
06 August 2020	The purpose of this amendment was to add a second interim analysis in response to the COVID-19 pandemic with the stopping boundary for the primary endpoint at one-sided alpha of 0.005.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

In this study there were 25 patients who did not take study treatment after randomization, and thus were not included in the safety set.
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Notes: