



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	Investigator, Monitor, Data analyst, Subject

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)
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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.

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
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End point description:

A confirmed composite endpoint includes cardiovascular (CV) death, heart failure (HF) hospitalization, or outpatient heart failure

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

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

Notes: