

**Clinical trial results:****A Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi-Center Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (HFREF) - Vericiguat GLOBAL Study in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA)****Summary**

EudraCT number	2016-000671-25
Trial protocol	DE SE CZ HU ES FR GB DK NL FI PL BE GR AT IT
Global end of trial date	02 September 2019

Results information

Result version number	v1 (current)
This version publication date	12 September 2020
First version publication date	12 September 2020

Trial information**Trial identification**

Sponsor protocol code	1242-001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02861534
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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	02 September 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 June 2019
Global end of trial reached?	Yes
Global end of trial date	02 September 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a randomized, placebo-controlled, parallel-group, multi-center, double-blind, event driven study of vericiguat (MK-1242) in participants with heart failure with reduced ejection fraction (HFrEF). The primary hypothesis is vericiguat (MK-1242) is superior to placebo in increasing the time to first occurrence of the composite of cardiovascular (CV) death or heart failure (HF) hospitalization in participants with HFrEF.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 September 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: 205
Country: Number of subjects enrolled	Australia: 48
Country: Number of subjects enrolled	Austria: 67
Country: Number of subjects enrolled	Belgium: 18
Country: Number of subjects enrolled	Canada: 145
Country: Number of subjects enrolled	Chile: 60
Country: Number of subjects enrolled	China: 315
Country: Number of subjects enrolled	Colombia: 224
Country: Number of subjects enrolled	Czech Republic: 110
Country: Number of subjects enrolled	Denmark: 53
Country: Number of subjects enrolled	Finland: 12
Country: Number of subjects enrolled	France: 76
Country: Number of subjects enrolled	Germany: 212
Country: Number of subjects enrolled	Greece: 70
Country: Number of subjects enrolled	Guatemala: 38
Country: Number of subjects enrolled	Hong Kong: 46
Country: Number of subjects enrolled	Hungary: 154
Country: Number of subjects enrolled	Ireland: 22

Country: Number of subjects enrolled	Israel: 218
Country: Number of subjects enrolled	Italy: 130
Country: Number of subjects enrolled	Japan: 319
Country: Number of subjects enrolled	Korea, Republic of: 83
Country: Number of subjects enrolled	Malaysia: 97
Country: Number of subjects enrolled	Mexico: 101
Country: Number of subjects enrolled	Netherlands: 42
Country: Number of subjects enrolled	New Zealand: 59
Country: Number of subjects enrolled	Norway: 22
Country: Number of subjects enrolled	Peru: 59
Country: Number of subjects enrolled	Philippines: 63
Country: Number of subjects enrolled	Poland: 302
Country: Number of subjects enrolled	Puerto Rico: 37
Country: Number of subjects enrolled	Russian Federation: 266
Country: Number of subjects enrolled	Singapore: 51
Country: Number of subjects enrolled	South Africa: 287
Country: Number of subjects enrolled	Spain: 116
Country: Number of subjects enrolled	Sweden: 62
Country: Number of subjects enrolled	Switzerland: 20
Country: Number of subjects enrolled	Taiwan: 102
Country: Number of subjects enrolled	Turkey: 196
Country: Number of subjects enrolled	Ukraine: 91
Country: Number of subjects enrolled	United Kingdom: 37
Country: Number of subjects enrolled	United States: 415
Worldwide total number of subjects	5050
EEA total number of subjects	1505

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)	1873
From 65 to 84 years	2894
85 years and over	283

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This trial enrolled participants with a history of chronic heart failure who were on standard therapy. Additional inclusion criteria applied.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Vericiguat

Arm description:

Participants received a starting dose of 2.5 mg of vericiguat taken orally once daily with food, on a background of heart failure (HF) standard of care. The vericiguat dose was uptitrated to 5 mg and to 10 mg.

Arm type	Experimental
Investigational medicinal product name	Vericiguat
Investigational medicinal product code	
Other name	MK-1242
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2.5, 5.0, or 10.0 mg orally once daily

Arm title	Placebo
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Arm description:

Participants received a starting matching placebo dose of 2.5 mg taken orally once daily with food, on a background of HF standard of care. The matching placebo dose was uptitrated to 5 mg and to 10 mg.

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

Dosage and administration details:

Matching placebo to vericiguat 2.5, 5.0, or 10.0 mg orally once daily

Number of subjects in period 1	Vericiguat	Placebo
Started	2526	2524
Treated	2519	2515
Completed	1952	1937
Not completed	574	587
Adverse event, serious fatal	541	552
Consent withdrawn by subject	15	18
Site Terminated by Sponsor	4	3
Lost to follow-up	14	14

Baseline characteristics

Reporting groups

Reporting group title	Vericiguat
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Reporting group description:

Participants received a starting dose of 2.5 mg of vericiguat taken orally once daily with food, on a background of heart failure (HF) standard of care. The vericiguat dose was uptitrated to 5 mg and to 10 mg.

Reporting group title	Placebo
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Reporting group description:

Participants received a starting matching placebo dose of 2.5 mg taken orally once daily with food, on a background of HF standard of care. The matching placebo dose was uptitrated to 5 mg and to 10 mg.

Reporting group values	Vericiguat	Placebo	Total
Number of subjects	2526	2524	5050
Age categorical			
Units: Subjects			

Age Continuous			
Units: Years			
arithmetic mean	67.5	67.2	-
standard deviation	± 12.2	± 12.2	
Sex: Female, Male			
Units: Participants			
Female	605	603	1208
Male	1921	1921	3842
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	24	28	52
Asian	571	561	1132
Native Hawaiian or Other Pacific Islander	3	11	14
Black or African American	123	126	249
White	1621	1618	3239
More than one race	183	180	363
Unknown or Not Reported	1	0	1

End points

End points reporting groups

Reporting group title	Vericiguat
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Reporting group description:

Participants received a starting dose of 2.5 mg of vericiguat taken orally once daily with food, on a background of heart failure (HF) standard of care. The vericiguat dose was uptitrated to 5 mg and to 10 mg.

Reporting group title	Placebo
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Reporting group description:

Participants received a starting matching placebo dose of 2.5 mg taken orally once daily with food, on a background of HF standard of care. The matching placebo dose was uptitrated to 5 mg and to 10 mg.

Primary: Time to First Occurrence of Composite Endpoint of Cardiovascular (CV) Death or Heart Failure (HF) Hospitalization

End point title	Time to First Occurrence of Composite Endpoint of Cardiovascular (CV) Death or Heart Failure (HF) Hospitalization
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End point description:

Time to First Occurrence of Composite Endpoint of CV Death or HF Hospitalization was analyzed using a one-sided stratified log-rank test. Randomized participants without any HF hospitalization or CV death event at the time of analysis were censored at their last available information, the date of their non-CV death, or the primary analysis database cutoff date of 18-June-2019, whichever occurred first. A clinical events committee (CEC) reviewed and adjudicated the endpoint events. A time-to-event methodology was used to evaluate the results; the incidence rate of participants with an event (number of participants with an event per 100 participant-years at risk) is provided. The analysis population for this end point included all randomized participants.

End point type	Primary
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End point timeframe:

Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2526	2524		
Units: Parts w/ event per 100 part-yrs at risk				
number (not applicable)	33.6	37.8		

Statistical analyses

Statistical analysis title	Time to First CV Death or HF Hospitalization
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Comparison groups	Vericiguat v Placebo
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Number of subjects included in analysis	5050
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019
Method	Cox proportional hazard model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	0.98

Secondary: Time to the First Occurrence of CV Death

End point title	Time to the First Occurrence of CV Death
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End point description:

Time to First Occurrence of CV Death was analyzed using a one-sided stratified log-rank test. Randomized participants without a CV death at the time of analysis were censored at their last available information, the date of their non-CV death, or the primary analysis database cutoff date of 18-June-2019, whichever occurred first. A CEC reviewed and adjudicated the endpoint events. A time-to-event methodology was used to evaluate the results; the incidence rate of participants with an event (number of participants with an event per 100 participant-years at risk) is provided. The analysis population for this end point included all randomized participants.

End point type	Secondary
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End point timeframe:

Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2526	2524		
Units: Parts w/ event per 100 part-yrs at risk				
number (not applicable)	12.9	13.9		

Statistical analyses

Statistical analysis title	Time to the First Occurrence of CV Death
Comparison groups	Vericiguat v Placebo
Number of subjects included in analysis	5050
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.269
Method	Cox proportional hazard model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.06

Secondary: Time to the First Occurrence of HF Hospitalization

End point title	Time to the First Occurrence of HF Hospitalization
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End point description:

Time to the First Occurrence of HF Hospitalization was analyzed using a one-sided stratified log-rank test. Randomized participants without any HF hospitalization at the time of analysis were censored at their last available information, the date of their death, or the primary analysis database cutoff date of 18-June-2019, whichever occurred first. A CEC reviewed and adjudicated the endpoint events. A time-to-event methodology was used to evaluate the results; the incidence rate of participants with an event (number of participants with an event per 100 participant-years at risk) is provided. The analysis population for this end point included all randomized participants.

End point type	Secondary
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End point timeframe:

Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2526	2524		
Units: Parts w/ event per 100 part-yrs at risk				
number (not applicable)	25.9	29.1		

Statistical analyses

Statistical analysis title	Time to the First Occurrence of HF Hospitalization
Comparison groups	Vericiguat v Placebo
Number of subjects included in analysis	5050
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.048
Method	Cox proportional hazard model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1

Secondary: Time to Total HF Hospitalizations (including first and recurrent events)

End point title	Time to Total HF Hospitalizations (including first and recurrent events)
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End point description:

Time to Total HF Hospitalizations (including first and recurring) was analyzed using an Andersen-Gill model. Randomized participants without any HF hospitalization at the time of analysis were censored at their last available information, the date of their death, or the primary analysis database cutoff date of 18-June-2019, whichever occurred first. A CEC reviewed and adjudicated the endpoint events. A time-to-event methodology was used to evaluate the results; the incidence rate of participants with an event (number of participants with an event per 100 participant-years of follow-up) is provided. The analysis population for this end point included all randomized participants.

End point type	Secondary
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End point timeframe:

Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2526	2524		
Units: Parts w/ event per 100 part-yrs				
number (not applicable)	38.3	42.4		

Statistical analyses

Statistical analysis title	Time to Total HF Hospitalizations
Comparison groups	Vericiguat v Placebo
Number of subjects included in analysis	5050
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023
Method	Andersen-Gill model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	0.99

Secondary: Time to First Occurrence of Composite Endpoint of All-Cause Mortality or HF Hospitalization

End point title	Time to First Occurrence of Composite Endpoint of All-Cause Mortality or HF Hospitalization
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End point description:

Time to First Occurrence of Composite Endpoint of All-Cause Mortality or HF Hospitalization was analyzed using a one-sided stratified log-rank test. Randomized participants without any all-cause mortality event or HF hospitalization at the time of analysis were censored at their last available information or the primary analysis database cutoff date of 18-June-2019, whichever occurred first. A CEC reviewed and adjudicated the endpoint events. A time-to-event methodology was used to evaluate the results; the incidence rate of participants with an event (number of participants with an event per 100 participant-years at risk) is provided. The analysis population for this end point included all randomized participants.

End point type	Secondary
End point timeframe:	Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2526	2524		
Units: Parts w/ event per 100 part-yrs at risk				
number (not applicable)	35.9	40.1		

Statistical analyses

Statistical analysis title	Time to All-Cause Mortality or HF Hospitalization
Comparison groups	Vericiguat v Placebo
Number of subjects included in analysis	5050
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.021
Method	Cox proportional hazard model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	0.98

Secondary: Time to All-Cause Mortality

End point title	Time to All-Cause Mortality
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End point description:

Time to All-Cause Mortality was analyzed using a one-sided stratified log-rank test. Randomized participants without any all-cause mortality event at the time of analysis were censored at their last available information or the primary analysis database cutoff date of 18-June-2019, whichever occurred first. A CEC reviewed and adjudicated the endpoint events. A time-to-event methodology was used to evaluate the results; the incidence rate of participants with an event (number of participants with an event per 100 participant-years at risk) is provided. The analysis population for this end point included all randomized participants.

End point type	Secondary
End point timeframe:	
Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)	

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2526	2524		
Units: Parts w/ event per 100 part-yrs at risk				
number (not applicable)	16.0	16.9		

Statistical analyses

Statistical analysis title	Time to All-Cause Mortality
Comparison groups	Vericiguat v Placebo
Number of subjects included in analysis	5050
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.377
Method	Cox proportional hazard model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.07

Secondary: Number of Participants Who Experienced One or More Adverse Events

End point title	Number of Participants Who Experienced One or More Adverse Events
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End point description:

An adverse event (AE) is any untoward medical occurrence in a study participant administered a pharmaceutical product that does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product. The analysis population for this end point included all randomized participants who received at least 1 dose of study treatment.

End point type	Secondary
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End point timeframe:

Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2519	2515		
Units: Participants	2027	2036		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Discontinued Treatment Due to an Adverse Event

End point title	Number of Participants Who Discontinued Treatment Due to an Adverse Event
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End point description:

An adverse event (AE) is any untoward medical occurrence in a study participant administered a pharmaceutical product that does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product. The analysis population for this end point included all randomized participants who received at least 1 dose of study treatment.

End point type	Secondary
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End point timeframe:

Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2519	2515		
Units: Participants	167	158		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Experienced Symptomatic Hypotension

End point title	Percentage of Participants Who Experienced Symptomatic Hypotension
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End point description:

Study participants were monitored for symptomatic hypotension, an event of clinical interest, and results were reported. The analysis population for this end point included all randomized participants who received at least 1 dose of study treatment.

End point type	Secondary
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End point timeframe:

Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2519	2515		
Units: Percentage of participants				
number (not applicable)	9.1	7.9		

Statistical analyses

Statistical analysis title	Pct of Parts Who Experienced Sympt Hypotension
Comparison groups	Vericiguat v Placebo
Number of subjects included in analysis	5034
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.121
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	2.8

Secondary: Percentage of Participants Who Experienced Syncope

End point title	Percentage of Participants Who Experienced Syncope
End point description:	Study participants were monitored for syncope, an event of clinical interest, and results were reported. The analysis population for this end point included all randomized participants who received at least 1 dose of study treatment.
End point type	Secondary
End point timeframe:	Up to approximately 33 months (through primary analysis database cutoff date of 18-June-2019)

End point values	Vericiguat	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2519	2515		
Units: Percentage of participants				
number (not applicable)	4.0	3.5		

Statistical analyses

Statistical analysis title	Pct of Participants Who Experienced Syncope
Comparison groups	Vericiguat v Placebo
Number of subjects included in analysis	5034
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.303
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	1.6

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 35 months (through Last Participant Last Visit date of 02-Sept-2019)

Adverse event reporting additional description:

Serious Adverse Events and Non-Serious Adverse Events: All randomized participants who received at least 1 dose of study treatment.

Number of Deaths (all causes): All randomized participants (n=2526, n=2524).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received a starting matching placebo dose of 2.5 mg taken orally once daily with food, on a background of HF standard of care. The matching placebo dose was uptitrated to 5 mg and to 10 mg.

Reporting group title	Vericiguat
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Reporting group description:

Participants received a starting dose of 2.5 mg of vericiguat taken orally once daily with food, on a background of HF standard of care. The vericiguat dose was uptitrated to 5 mg and to 10 mg.

Serious adverse events	Placebo	Vericiguat	
Total subjects affected by serious adverse events			
subjects affected / exposed	897 / 2515 (35.67%)	852 / 2519 (33.82%)	
number of deaths (all causes)	561	553	
number of deaths resulting from adverse events	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	1 / 2515 (0.04%)	3 / 2519 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal gland cancer metastatic		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Angiocentric lymphoma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastric neoplasm		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bowen's disease		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	4 / 2515 (0.16%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Chronic lymphocytic leukaemia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Colon neoplasm		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cutaneous T-cell lymphoma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric cancer		
subjects affected / exposed	1 / 2515 (0.04%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Glioblastoma multiforme		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic cancer		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer metastatic		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatic neoplasm		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatobiliary cancer		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inflammatory pseudotumour		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung neoplasm malignant		
subjects affected / exposed	4 / 2515 (0.16%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Lymphoma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoproliferative disorder		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		

subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to abdominal cavity			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lung			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lymph nodes			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myelodysplastic syndrome			

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal cancer		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal squamous cell carcinoma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma metastatic		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Plasma cell myeloma		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Plasmacytoma		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Polycythaemia vera		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	5 / 2515 (0.20%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	0 / 2515 (0.00%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal cancer		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Squamous cell carcinoma of head and neck		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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 of the oral cavity		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sweat gland tumour		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
T-cell lymphoma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Tongue neoplasm malignant stage unspecified		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour ulceration			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Uterine cancer			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Waldenstrom's macroglobulinaemia			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial occlusive disease			

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bleeding varicose vein		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Deep vein thrombosis		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	2 / 2515 (0.08%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic vasculitis		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	4 / 2515 (0.16%)	5 / 2519 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	5 / 2515 (0.20%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	44 / 2515 (1.75%)	33 / 2519 (1.31%)
occurrences causally related to treatment / all	10 / 45	9 / 34
deaths causally related to treatment / all	0 / 0	0 / 1
Hypovolaemic shock		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery occlusion		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphorrhoea		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	1 / 2515 (0.04%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	1 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	11 / 2515 (0.44%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	3 / 2515 (0.12%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Peripheral vascular disorder		

subjects affected / exposed	3 / 2515 (0.12%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Shock haemorrhagic			
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein ruptured			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular occlusion			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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			
Aortic aneurysm repair			

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia prophylaxis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac pacemaker replacement		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac rehabilitation therapy		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac resynchronisation therapy		
subjects affected / exposed	7 / 2515 (0.28%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular event prophylaxis		
subjects affected / exposed	4 / 2515 (0.16%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardioversion		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Central venous catheter removal		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrectomy		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implantable defibrillator insertion		
subjects affected / exposed	2 / 2515 (0.08%)	5 / 2519 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Implantable defibrillator removal		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implantable defibrillator replacement		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia repair		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intraocular lens implant		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leg amputation		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephroprotective therapy		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Therapeutic procedure		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toe operation			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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			
Asthenia			
subjects affected / exposed	6 / 2515 (0.24%)	6 / 2519 (0.24%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac complication associated with device			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	8 / 2515 (0.32%)	10 / 2519 (0.40%)	
occurrences causally related to treatment / all	0 / 14	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related thrombosis			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Discomfort			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			

subjects affected / exposed	1 / 2515 (0.04%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised oedema		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site erythema		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site haematoma		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza like illness		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device pain		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site haematoma		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site swelling		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site thrombosis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	4 / 2515 (0.16%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	7 / 2515 (0.28%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	3 / 2515 (0.12%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Physical deconditioning		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sensation of foreign body		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated hernia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
UGT1A1 gene polymorphism		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent occlusion		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent thrombosis		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Amyloidosis			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	8 / 2515 (0.32%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	1 / 2515 (0.04%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	7 / 2515 (0.28%)	9 / 2519 (0.36%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 2	
Asthma			
subjects affected / exposed	4 / 2515 (0.16%)	6 / 2519 (0.24%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	30 / 2515 (1.19%)	38 / 2519 (1.51%)
occurrences causally related to treatment / all	0 / 50	0 / 51
deaths causally related to treatment / all	0 / 0	0 / 3
Chylothorax		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cough		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	7 / 2515 (0.28%)	11 / 2519 (0.44%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		

subjects affected / exposed	3 / 2515 (0.12%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperventilation		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive airways disorder		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		

subjects affected / exposed	13 / 2515 (0.52%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 15	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Pleurisy		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	2 / 2515 (0.08%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	4 / 2515 (0.16%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	6 / 2515 (0.24%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Pulmonary haematoma		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary infarction		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	3 / 2515 (0.12%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory disorder		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	5 / 2515 (0.20%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rhinitis hypertrophic		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep apnoea syndrome		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillar haemorrhage		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Delirium			
subjects affected / exposed	3 / 2515 (0.12%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug use disorder			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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 / 2515 (0.08%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device battery issue			
subjects affected / exposed	4 / 2515 (0.16%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device ineffective			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	4 / 2515 (0.16%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lead dislodgement			

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	3 / 2515 (0.12%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biloma			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	4 / 2515 (0.16%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	6 / 2515 (0.24%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cholecystitis chronic			

subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	2 / 2515 (0.08%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic hepatic failure			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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 / 2515 (0.04%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic congestion			
subjects affected / exposed	0 / 2515 (0.00%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis toxic			

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular injury			
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	2 / 2515 (0.08%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	2 / 2515 (0.08%)	5 / 2519 (0.20%)	
occurrences causally related to treatment / all	0 / 2	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portosplenomesenteric venous thrombosis			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiocardiogram			

subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anticoagulation drug level above therapeutic		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aspartate aminotransferase increased		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood bilirubin increased		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatinine increased		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium increased		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood sodium decreased		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urea increased		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone density abnormal		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac index abnormal		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Catheterisation cardiac		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cortisol decreased		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	3 / 2515 (0.12%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gamma-glutamyltransferase increased		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate irregular		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme abnormal		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		
subjects affected / exposed	2 / 2515 (0.08%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza A virus test positive		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test abnormal		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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 increased		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Occult blood positive		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	1 / 2515 (0.04%)	0 / 2519 (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 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Weight increased			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial bypass occlusion			

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula site complication		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Asbestosis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone fissure		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burns second degree		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burns third degree		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac valve replacement complication		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	0 / 2515 (0.00%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary vascular graft stenosis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Costal cartilage fracture		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	5 / 2515 (0.20%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 5	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		

subjects affected / exposed	8 / 2515 (0.32%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Femur fracture		
subjects affected / exposed	12 / 2515 (0.48%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 12	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Fibula fracture		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	1 / 2515 (0.04%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Heat illness		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	3 / 2515 (0.12%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	3 / 2515 (0.12%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site haemorrhage		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	5 / 2515 (0.20%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Penis injury		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural hypothyroidism		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative hypotension		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis fracture		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		

subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Sedation complication		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		
subjects affected / exposed	0 / 2515 (0.00%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Snake bite		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		

subjects affected / exposed	1 / 2515 (0.04%)	6 / 2519 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subdural haemorrhage			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suture related complication			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	6 / 2515 (0.24%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Traumatic fracture			

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic liver injury		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic ulcer		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention postoperative		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	3 / 2515 (0.12%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vasoplegia syndrome		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wrist fracture		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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			
Corneal dystrophy			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyloric stenosis			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	4 / 2515 (0.16%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	5 / 2515 (0.20%)	5 / 2519 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	

Angina pectoris			
subjects affected / exposed	8 / 2515 (0.32%)	9 / 2519 (0.36%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	7 / 2515 (0.28%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 13	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve calcification			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	3 / 2515 (0.12%)	3 / 2519 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	29 / 2515 (1.15%)	14 / 2519 (0.56%)	
occurrences causally related to treatment / all	0 / 31	0 / 15	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrial flutter			

subjects affected / exposed	7 / 2515 (0.28%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Atrial tachycardia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial thrombosis		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	3 / 2515 (0.12%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		

subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	3 / 2515 (0.12%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiac asthma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		
subjects affected / exposed	116 / 2515 (4.61%)	82 / 2519 (3.26%)
occurrences causally related to treatment / all	1 / 128	0 / 88
deaths causally related to treatment / all	0 / 16	0 / 9
Cardiac failure acute		
subjects affected / exposed	4 / 2515 (0.16%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Cardiac failure chronic		
subjects affected / exposed	10 / 2515 (0.40%)	5 / 2519 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		
subjects affected / exposed	25 / 2515 (0.99%)	13 / 2519 (0.52%)
occurrences causally related to treatment / all	0 / 25	0 / 13
deaths causally related to treatment / all	0 / 4	0 / 1
Cardiac perforation		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ventricular thrombosis		

subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	1 / 2515 (0.04%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	4 / 2515 (0.16%)	8 / 2519 (0.32%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 2
Cardiopulmonary failure		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiorenal syndrome		
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular disorder		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular insufficiency		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	3 / 2515 (0.12%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		

subjects affected / exposed	3 / 2515 (0.12%)	7 / 2519 (0.28%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart valve incompetence		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		

subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Mitral valve incompetence		
subjects affected / exposed	5 / 2515 (0.20%)	7 / 2519 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		
subjects affected / exposed	3 / 2515 (0.12%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 3	0 / 2
Myocardial ischaemia		
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		

subjects affected / exposed	2 / 2515 (0.08%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular dysfunction			
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	2 / 2515 (0.08%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	7 / 2515 (0.28%)	9 / 2519 (0.36%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			

subjects affected / exposed	27 / 2515 (1.07%)	14 / 2519 (0.56%)	
occurrences causally related to treatment / all	0 / 29	5 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic neuropathy			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Axonal neuropathy			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain hypoxia			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	3 / 2515 (0.12%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery embolism		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebral artery stenosis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebral infarction		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	6 / 2515 (0.24%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Cerebrovascular disorder		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Dementia Alzheimer's type		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	2 / 2515 (0.08%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 2	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		

subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (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	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hydrocephalus		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		

subjects affected / exposed	2 / 2515 (0.08%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Lethargy		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myoclonus		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post stroke epilepsy		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	0 / 2515 (0.00%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	2 / 2515 (0.08%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Spinal cord compression		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Syncope		

subjects affected / exposed	33 / 2515 (1.31%)	43 / 2519 (1.71%)	
occurrences causally related to treatment / all	2 / 35	2 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic encephalopathy			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	2 / 2515 (0.08%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	24 / 2515 (0.95%)	41 / 2519 (1.63%)	
occurrences causally related to treatment / all	0 / 25	0 / 50	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of chronic disease			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bicytopenia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood loss anaemia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone marrow failure		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulopathy		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Disseminated intravascular coagulation		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocoagulable state		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 2515 (0.04%)	3 / 2519 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	7 / 2515 (0.28%)	3 / 2519 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	3 / 2515 (0.12%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Blindness			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			

subjects affected / exposed	6 / 2515 (0.24%)	9 / 2519 (0.36%)
occurrences causally related to treatment / all	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye haemorrhage		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid ptosis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular cyst		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery thrombosis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	4 / 2515 (0.16%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	3 / 2515 (0.12%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal rigidity			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic pancreatitis			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorectal ulcer			

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	4 / 2515 (0.16%)	8 / 2519 (0.32%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	2 / 2515 (0.08%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dental caries		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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 / 2515 (0.04%)	0 / 2519 (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	7 / 2515 (0.28%)	10 / 2519 (0.40%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	3 / 2515 (0.12%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric perforation		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		

subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	7 / 2515 (0.28%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	7 / 2515 (0.28%)	12 / 2519 (0.48%)
occurrences causally related to treatment / all	0 / 7	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal toxicity		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	4 / 2515 (0.16%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gingival bleeding		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		

subjects affected / exposed	3 / 2515 (0.12%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated umbilical hernia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	9 / 2515 (0.36%)	11 / 2519 (0.44%)
occurrences causally related to treatment / all	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia strangulated		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia, obstructive		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal infarction		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Intestinal obstruction		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haematoma		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic enteritis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal haemorrhage		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal obstruction		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal stenosis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer perforation		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		

subjects affected / exposed	4 / 2515 (0.16%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive pancreatitis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal achalasia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stenosis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatolithiasis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumatosis intestinalis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	1 / 2515 (0.04%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		

subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
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	6 / 2515 (0.24%)	3 / 2519 (0.12%)	
occurrences causally related to treatment / all	0 / 6	1 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vomiting			
subjects affected / exposed	2 / 2515 (0.08%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis bullous			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	4 / 2515 (0.16%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug eruption			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ecchymosis			

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage subcutaneous		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Henoch-Schonlein purpura		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurodermatitis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin necrosis		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer		
subjects affected / exposed	9 / 2515 (0.36%)	5 / 2519 (0.20%)
occurrences causally related to treatment / all	0 / 14	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Stasis dermatitis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stevens-Johnson syndrome		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Urticaria			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	51 / 2515 (2.03%)	66 / 2519 (2.62%)	
occurrences causally related to treatment / all	4 / 53	6 / 69	
deaths causally related to treatment / all	0 / 4	1 / 6	
Azotaemia			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder cyst			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder mass			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	31 / 2515 (1.23%)	40 / 2519 (1.59%)	
occurrences causally related to treatment / all	0 / 31	2 / 42	
deaths causally related to treatment / all	0 / 1	0 / 2	
Costovertebral angle tenderness			

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Haematuria		
subjects affected / exposed	7 / 2515 (0.28%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 7	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Nephritis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	1 / 2515 (0.04%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	30 / 2515 (1.19%)	24 / 2519 (0.95%)
occurrences causally related to treatment / all	1 / 31	1 / 25
deaths causally related to treatment / all	0 / 0	0 / 2
Renal impairment		
subjects affected / exposed	7 / 2515 (0.28%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Renal infarct		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urate nephropathy		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	2 / 2515 (0.08%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid syndrome			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Glucocorticoid deficiency			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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 / 2515 (0.04%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoparathyroidism secondary			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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			

Arthralgia			
subjects affected / exposed	1 / 2515 (0.04%)	4 / 2519 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	3 / 2515 (0.12%)	6 / 2519 (0.24%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondritis			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	6 / 2515 (0.24%)	7 / 2519 (0.28%)	
occurrences causally related to treatment / all	2 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty tophus			
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma muscle			

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	5 / 2515 (0.20%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	4 / 2515 (0.16%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	0 / 2515 (0.00%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	3 / 2515 (0.12%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sjogren's syndrome		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	3 / 2515 (0.12%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal stenosis		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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 limb			
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acinetobacter bacteraemia			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Amoebic dysentery			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula site infection			

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	7 / 2515 (0.28%)	10 / 2519 (0.40%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis viral		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	19 / 2515 (0.76%)	25 / 2519 (0.99%)
occurrences causally related to treatment / all	0 / 20	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis gangrenous		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chest wall abscess			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complicated appendicitis			
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis bacterial			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			

subjects affected / exposed	2 / 2515 (0.08%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (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	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated tuberculosis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Endocarditis		
subjects affected / exposed	1 / 2515 (0.04%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 2
Enteritis infectious		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter bacteraemia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal bacteraemia		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal infection		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis viral		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	6 / 2515 (0.24%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural abscess		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye infection bacterial		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile infection		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fungaemia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	4 / 2515 (0.16%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gas gangrene		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	10 / 2515 (0.40%)	16 / 2519 (0.64%)
occurrences causally related to treatment / all	0 / 10	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis norovirus		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
H1N1 influenza		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma infection		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site cellulitis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	3 / 2515 (0.12%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infected bite		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	3 / 2515 (0.12%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	3 / 2515 (0.12%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	8 / 2515 (0.32%)	11 / 2519 (0.44%)
occurrences causally related to treatment / all	0 / 8	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 1
Intervertebral discitis		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal sepsis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Klebsiella sepsis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	4 / 2515 (0.16%)	7 / 2519 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection viral		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	3 / 2515 (0.12%)	10 / 2519 (0.40%)
occurrences causally related to treatment / all	0 / 3	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Measles		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site abscess		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocarditis infectious		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nosocomial infection		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes zoster		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	6 / 2515 (0.24%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Osteomyelitis acute		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parainfluenzae virus infection		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parotid abscess		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontitis		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perirectal abscess		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis bacterial		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pertussis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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	116 / 2515 (4.61%)	104 / 2519 (4.13%)
occurrences causally related to treatment / all	0 / 127	0 / 113
deaths causally related to treatment / all	0 / 15	0 / 8
Pneumonia bacterial		
subjects affected / exposed	4 / 2515 (0.16%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia chlamydial		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia mycoplasmal		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (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 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia respiratory syncytial viral		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia staphylococcal		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		

subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoas abscess		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		
subjects affected / exposed	3 / 2515 (0.12%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Pyelonephritis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal abscess		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	4 / 2515 (0.16%)	5 / 2519 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Respiratory tract infection viral		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonella bacteraemia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	25 / 2515 (0.99%)	16 / 2519 (0.64%)
occurrences causally related to treatment / all	0 / 25	0 / 16
deaths causally related to treatment / all	0 / 7	0 / 5
Septic shock		
subjects affected / exposed	14 / 2515 (0.56%)	11 / 2519 (0.44%)
occurrences causally related to treatment / all	0 / 14	0 / 11
deaths causally related to treatment / all	0 / 3	0 / 5
Serratia bacteraemia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin bacterial infection		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		

subjects affected / exposed	2 / 2515 (0.08%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal skin infection		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic candida		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Thrombophlebitis septic		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculous pleurisy		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Typhoid fever		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	10 / 2515 (0.40%)	11 / 2519 (0.44%)
occurrences causally related to treatment / all	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Ureter abscess		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	16 / 2515 (0.64%)	20 / 2519 (0.79%)
occurrences causally related to treatment / all	0 / 18	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	0 / 2515 (0.00%)	7 / 2519 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Vestibular neuronitis		

subjects affected / exposed	2 / 2515 (0.08%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral diarrhoea			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2515 (0.00%)	3 / 2519 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
West Nile viral infection			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	4 / 2515 (0.16%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (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			
Cachexia			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			

subjects affected / exposed	12 / 2515 (0.48%)	7 / 2519 (0.28%)
occurrences causally related to treatment / all	0 / 13	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus		
subjects affected / exposed	10 / 2515 (0.40%)	5 / 2519 (0.20%)
occurrences causally related to treatment / all	0 / 11	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes with hyperosmolarity		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	2 / 2515 (0.08%)	4 / 2519 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	1 / 2515 (0.04%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	12 / 2515 (0.48%)	10 / 2519 (0.40%)
occurrences causally related to treatment / all	1 / 14	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperammonaemia		

subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	1 / 2515 (0.04%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	4 / 2515 (0.16%)	6 / 2519 (0.24%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	2 / 2515 (0.08%)	3 / 2519 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Hyperkalaemia		
subjects affected / exposed	14 / 2515 (0.56%)	13 / 2519 (0.52%)
occurrences causally related to treatment / all	0 / 14	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Hypernatraemia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperosmolar state		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoalbuminaemia		
subjects affected / exposed	2 / 2515 (0.08%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		

subjects affected / exposed	0 / 2515 (0.00%)	2 / 2519 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochloraemia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	9 / 2515 (0.36%)	12 / 2519 (0.48%)
occurrences causally related to treatment / all	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	7 / 2515 (0.28%)	7 / 2519 (0.28%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Hypomagnesaemia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	5 / 2515 (0.20%)	5 / 2519 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypophosphataemia		
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ketoacidosis		

subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Marasmus			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metabolic acidosis			
subjects affected / exposed	4 / 2515 (0.16%)	2 / 2519 (0.08%)	
occurrences causally related to treatment / all	0 / 4	1 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
Metabolic alkalosis			
subjects affected / exposed	1 / 2515 (0.04%)	0 / 2519 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mineral metabolism disorder			
subjects affected / exposed	0 / 2515 (0.00%)	1 / 2519 (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	8 / 2515 (0.32%)	5 / 2519 (0.20%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Vericiguat	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	925 / 2515 (36.78%)	958 / 2519 (38.03%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	331 / 2515 (13.16%)	369 / 2519 (14.65%)	
occurrences (all)	437	487	
Cardiac disorders			

Cardiac failure subjects affected / exposed occurrences (all)	157 / 2515 (6.24%) 221	160 / 2519 (6.35%) 219	
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	152 / 2515 (6.04%) 169	169 / 2519 (6.71%) 195	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	134 / 2515 (5.33%) 139	165 / 2519 (6.55%) 181	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	120 / 2515 (4.77%) 136	127 / 2519 (5.04%) 141	
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	132 / 2515 (5.25%) 158	127 / 2519 (5.04%) 161	
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	131 / 2515 (5.21%) 163	126 / 2519 (5.00%) 153	
Metabolism and nutrition disorders Hyperkalaemia subjects affected / exposed occurrences (all)	138 / 2515 (5.49%) 167	112 / 2519 (4.45%) 124	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 June 2016	Amendment 01: The primary reason for this amendment was to update the Exclusion Criteria.
27 March 2017	Amendment 04: The primary reason for this amendment was to update the following sections of the protocol: Rationale for the Trial and Selected Patient Population; Clinical Criteria for Early Trial Termination; Statistical Analysis Plan Summary; Futility Interim Analysis; and Efficacy Interim Analysis.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported