Clinical trial results:
A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Subjects with Acute Coronary Syndrome

Summary

EudraCT number	2017-000996-98
Trial protocol	GB LV SE PT FI BE LT DK EE DE AT CZ NO HU FR NL ES SK BG GR HR IT RO
Global end of trial date	17 November 2023

Results information

Result version number	v1
This version publication date	20 October 2024
First version publication date	20 October 2024

Trial information

Trial identification

Sponsor protocol code	CSL112_3001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03473223
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CSL Behring LLC
Sponsor organisation address	1020 First Avenue, King of Prussia, PA, United States, 19406-0901
Public contact	Trial Registration Coordinator, CSL Behring LLC, +1 610-878-4000, clinicaltrials@cslbehring.com
Scientific contact	Trial Registration Coordinator, CSL Behring LLC, +1 610-878-4000, clinicaltrials@cslbehring.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	24 January 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the efficacy of CSL112 in reducing the risk of Major adverse cardiovascular event (MACE) (cardiovascular [CV] death, myocardial infarction [MI], or stroke) from the time of randomisation through 90 days in subjects with acute coronary syndrome (ACS) (diagnosed with ST-segment elevation myocardial infarction [STEMI] or Non-ST-segment elevation myocardial infarction [NSTEMI]).

Protection of trial subjects:

This study was carried out in accordance with the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, the ethical principles that have their origin in the Declaration of Helsinki, all applicable national and local regulations, and standard operating procedures for clinical research and development at CSL Behring (CSL). The study protocol and all amendments were approved by the Independent Ethics Committee (IEC) of the participating center. Before any protocol-specific procedures were carried out, participants were informed, in an understandable form, about the nature, scope, and possible consequences of the study. Participant informed consent was obtained and documented according to the provisions of ICH GCP and applicable regulatory requirements. Written informed consent was provided by each participant before any protocol-specific procedures were carried out.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	21 March 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 869
Country: Number of subjects enrolled	Australia: 329
Country: Number of subjects enrolled	Brazil: 1553
Country: Number of subjects enrolled	Canada: 508
Country: Number of subjects enrolled	Chile: 53
Country: Number of subjects enrolled	Colombia: 137
Country: Number of subjects enrolled	Georgia: 178
Country: Number of subjects enrolled	Hong Kong: 35
Country: Number of subjects enrolled	Israel: 1015

Country: Number of subjects enrolled	Japan: 322
Country: Number of subjects enrolled	Malaysia: 278
Country: Number of subjects enrolled	Mexico: 283
Country: Number of subjects enrolled	New Zealand: 101
Country: Number of subjects enrolled	Peru: 14
Country: Number of subjects enrolled	Russian Federation: 878
Country: Number of subjects enrolled	Serbia: 511
Country: Number of subjects enrolled	Singapore: 39
Country: Number of subjects enrolled	South Africa: 100
Country: Number of subjects enrolled	Netherlands: 1486
Country: Number of subjects enrolled	Norway: 36
Country: Number of subjects enrolled	Poland: 1006
Country: Number of subjects enrolled	Portugal: 151
Country: Number of subjects enrolled	Romania: 764
Country: Number of subjects enrolled	Slovakia: 16
Country: Number of subjects enrolled	Spain: 167
Country: Number of subjects enrolled	Sweden: 26
Country: Number of subjects enrolled	United Kingdom: 99
Country: Number of subjects enrolled	Croatia: 40
Country: Number of subjects enrolled	Austria: 122
Country: Number of subjects enrolled	Belgium: 178
Country: Number of subjects enrolled	Bulgaria: 553
Country: Number of subjects enrolled	Czechia: 106
Country: Number of subjects enrolled	Denmark: 177
Country: Number of subjects enrolled	Estonia: 149
Country: Number of subjects enrolled	Finland: 24
Country: Number of subjects enrolled	France: 193
Country: Number of subjects enrolled	Germany: 337
Country: Number of subjects enrolled	Greece: 152
Country: Number of subjects enrolled	Hungary: 904
Country: Number of subjects enrolled	Italy: 181
Country: Number of subjects enrolled	Latvia: 69
Country: Number of subjects enrolled	Lithuania: 210
Country: Number of subjects enrolled	Korea, Republic of: 194
Country: Number of subjects enrolled	Switzerland: 172
Country: Number of subjects enrolled	Taiwan: 194
Country: Number of subjects enrolled	Thailand: 281
Country: Number of subjects enrolled	Türkiye: 450
Country: Number of subjects enrolled	Ukraine: 734
Country: Number of subjects enrolled	United States: 1845
Worldwide total number of subjects	18219
EEA total number of subjects	7047

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	7460
From 65 to 84 years	10435
85 years and over	324

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 897 centers across 5 regions (North America, Latin America, Western Europe, Central and Eastern Europe, and Asia Pacific).

Pre-assignment

Screening details:

A total of 18,848 participants were screened, with 622 identified as screen failures. Of the screened participants, 18,226 were randomized in 1:1 ratio to receive study interventions (CSL112 or Placebo), and 7 of these randomized participants were excluded from analysis because of concerns with respect to the quality of the data at one study site.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	CSL112

Arm description:

Participants received 6 grams of CSL112 (apoA-I purified from human plasma) once weekly via IV infusion for up to 4 weeks.

Arm type	Experimental
Investigational medicinal product name	Apolipoprotein A-I [human] (apoA-I)
Investigational medicinal product code	CSL112
Other name	CSL112
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Apolipoprotein A-I [human] (apoA-I) purified from human plasma for intravenous administration.

Arm title	Placebo

Arm description:

Participants received placebo (25% albumin solution diluted to 4.4%) once weekly via IV infusion for up to 4 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

25% albumin solution diluted to 4.4% was administered IV at the same volume and duration as that of CSL112.

Number of subjects in period 1	CSL112	Placebo
Started	9112	9107
Safety Analysis Set (SAS)	9010	9027
Completed	9002	9020
Not completed	110	87
Indirect contact	32	29
Other-unspecified	30	15
Withdrawal by Subject	47	42
Lost to follow-up	1	1

Baseline characteristics

Reporting groups	
Reporting group title	CSL112
Reporting group description:	
Participants received 6 grams of CSL112 (apoA-I purified from human plasma) once weekly via IV infusion for up to 4 weeks.	

Reporting group title	Placebo
Reporting group description:	
Participants received placebo (25% albumin solution diluted to 4.4%) once weekly via IV infusion for up to 4 weeks.	

Reporting group values	CSL112	Placebo	Total
Number of subjects	9112	9107	18219
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	65.6	65.4	
standard deviation	± 10.09	± 10.21	-
Gender categorical			
Units: Subjects			
Female	2326	2386	4712
Male	6786	6721	13507
Ethnicity			
Units: Subjects			
Hispanic or Latino	1566	1596	3162
Not Hispanic or Latino	7410	7383	14793
Unknown or Not Reported	136	128	264
Race			
Units: Subjects			
American Indian or Alaska Native	51	36	87
Asian	743	781	1524
Native Hawaiian or Other Pacific Islander	8	10	18
Black or African American	181	181	362
White	7769	7698	15467
Multiracial or other	314	356	670
Unknown or Not Reported	46	45	91

End points

End points reporting groups

Reporting group title	CSL112

Reporting group description:

Participants received 6 grams of CSL112 (apoA-I purified from human plasma) once weekly via IV infusion for up to 4 weeks.

Reporting group title	Placebo

Reporting group description:

Participants received placebo (25% albumin solution diluted to 4.4%) once weekly via IV infusion for up to 4 weeks.

Primary: Number of Participants With First Occurrence of Any Component of Composite MACE (CV Death, MI, or Stroke)

End point title	Number of Participants With First Occurrence of Any Component of Composite MACE (CV Death, MI, or Stroke)

End point description:

MACE (Major adverse cardiovascular event[s])(CV [cardiovascular] death, MI [Myocardial Infarction], or stroke). Analysis was performed on the intent-to-treat (ITT) analysis set. The ITT analysis set comprised all randomized participants with the exception of participants enrolled at site(s) excluded from analysis due to concerns regarding data integrity. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Primary

End point timeframe:

From the time of randomization through 90 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9112	9107		
Units: participants	439	472		

Statistical analyses

Statistical analysis title	CSL112 versus Placebo
Comparison groups	CSL112 v Placebo
Number of subjects included in analysis	18219
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.121 [1]
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.925

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8126
upper limit	1.0538

Notes:

[1] - 1-sided p-value.

Secondary: Total Number of Hospitalizations for Coronary, Cerebral, or Peripheral Ischemia

End point title	Total Number of Hospitalizations for Coronary, Cerebral, or Peripheral Ischemia

End point description:

The total number of hospitalizations and individual hospitalizations due to coronary, cerebral, and peripheral ischemia were reported. Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of participants enrolled at site(s) excluded from analysis due to concerns regarding data integrity. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary

End point timeframe:

From the time of randomization through 90 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9112	9107		
Units: hospitalizations				
number (not applicable)				
Total hospitalizations	433	442		
Coronary ischemia	367	376		
Cerebral ischemia	39	36		
Peripheral ischemia	27	30		

Statistical analyses

Statistical analysis title	CSL112 versus Placebo
Comparison groups	CSL112 v Placebo
Number of subjects included in analysis	18219
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.341 [2]
Method	Negative binomial regression model
Parameter estimate	Rate ratio
Point estimate	0.971

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8442
upper limit	1.1171

Notes:

[2] - 1-sided p-value.

Secondary: Number of Participants With First Occurrence of CV Death, MI, or Stroke

End point title	Number of Participants With First Occurrence of CV Death, MI, or Stroke

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of participants enrolled at site(s) excluded from analysis due to concerns regarding data integrity. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary

End point timeframe:

From the time of randomization through 180 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9112	9107		
Units: participants	622	683		

Statistical analyses

Statistical analysis title	CSL112 versus Placebo
Comparison groups	CSL112 v Placebo
Number of subjects included in analysis	18219
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.038
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.907
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8132
upper limit	1.0106

Notes:

[3] - 1-sided p-value.

Secondary: Number of Participants With First Occurrence of CV Death, MI, or Stroke

End point title	Number of Participants With First Occurrence of CV Death, MI,

	or Stroke

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of participants enrolled at site(s) excluded from analysis due to concerns regarding data integrity. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary

End point timeframe:

From the time of randomization through 365 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9112	9107		
Units: participants	885	944		

Statistical analyses

Statistical analysis title	CSL112 versus Placebo
Comparison groups	CSL112 v Placebo
Number of subjects included in analysis	18219
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.069 [4]
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.933
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8511
upper limit	1.0224

Notes:

[4] - 1-sided p-value.

Secondary: Number of Participants With Occurrence of CV Death

End point title	Number of Participants With Occurrence of CV Death

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of participants enrolled at site(s) excluded from analysis due to concerns regarding data integrity. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary

End point timeframe:

From the time of randomization through 90 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9112	9107		
Units: participants	107	128		

Statistical analyses

Statistical analysis title	CSL112 versus Placebo
Comparison groups	CSL112 v Placebo
Number of subjects included in analysis	18219
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.074 [5]
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.827
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6399
upper limit	1.0695

Notes:

[5] - 1-sided p-value.

Secondary: Number of Participants With First Occurrence of MI

End point title	Number of Participants With First Occurrence of MI

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of participants enrolled at site(s) excluded from analysis due to concerns regarding data integrity. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary

End point timeframe:

From the time of randomization through 90 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9112	9107		
Units: participants	312	342		

Statistical analyses

Statistical analysis title	CSL112 versus Placebo
Comparison groups	CSL112 v Placebo
Number of subjects included in analysis	18219
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.113 [6]
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.909
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7801
upper limit	1.0603

Notes:

[6] - 1-sided p-value.

Secondary: Number of Participants With First Occurrence of Stroke	
End point title	Number of Participants With First Occurrence of Stroke

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of participants enrolled at site(s) excluded from analysis due to concerns regarding data integrity. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary

End point timeframe:

From the time of randomization through 90 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9112	9107		
Units: participants	57	49		

Statistical analyses

Statistical analysis title	CSL112 versus Placebo
Comparison groups	CSL112 v Placebo
Number of subjects included in analysis	18219
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.767 [7]
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	1.153

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7867
upper limit	1.6886

Notes:

[7] - 1-sided p-value.

Secondary: Number of Participants With First Occurrence of CV Death, Type 1 MI or Stroke

End point title	Number of Participants With First Occurrence of CV Death, Type 1 MI or Stroke

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of participants enrolled at site(s) excluded from analysis due to concerns regarding data integrity. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary

End point timeframe:

From the time of randomization through 90, 180 and 365 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9112	9107		
Units: participants				
Through Day 90	272	308		
Through Day 180	400	444		
Through Day 365	594	639		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Occurrence of All-cause Death

End point title	Number of Participants With Occurrence of All-cause Death

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of participants enrolled at site(s) excluded from analysis due to concerns regarding data integrity. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary

End point timeframe:

From the time of randomization through 365 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9112	9107		
Units: participants	341	345		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Adverse Events

End point title	Number of Participants With Adverse Events

End point description:

An AE was defined as any unfavorable and unintended sign (including an abnormal, clinically significant laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product. Analysis was performed on the Safety analysis set (SAS). The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

End point type	Secondary

End point timeframe:

From the start of treatment through 90 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9010	9027		
Units: participants	3938	3927		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Adverse Events

End point title	Percentage of Participants With Adverse Events

End point description:

An AE was defined as any unfavorable and unintended sign (including an abnormal, clinically significant laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

End point type	Secondary

End point timeframe:

From the start of treatment through 90 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9010	9027		
Units: percentage of participants				
number (not applicable)	43.7	43.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-related Adverse Events

End point title	Number of Participants With Treatment-related Adverse Events

End point description:

Treatment-related AEs were AEs considered by the Investigator to have a causal relationship to the investigational product. Analysis was performed on the SAS.The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

End point type	Secondary

End point timeframe:

From the start of treatment through 365 days (end of study)

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9010	9027		
Units: participants	350	304		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Treatment-related Adverse Events

End point title	Percentage of Participants With Treatment-related Adverse Events

End point description:

Treatment-related AEs were AEs considered by the Investigator to have a causal relationship to the investigational product. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

End point type	Secondary

End point timeframe:

From the start of treatment through 365 days (end of study)

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9010	9027		
Units: percentage of participants				
number (not applicable)	3.9	3.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Serious Adverse Events (SAEs)

End point title	Number of Participants With Serious Adverse Events (SAEs)

End point description:

SAE was defined as any untoward medical occurrence that at any dose: results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect or is a medically significant event. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

End point type	Secondary

End point timeframe:

From the start of treatment through 365 days (end of study)

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9010	9027		
Units: participants	1514	1557		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SAEs

End point title	Percentage of Participants With SAEs

End point description:

SAE was defined as any untoward medical occurrence that at any dose: results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect or is a medically significant event. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

End point type	Secondary

End point timeframe:

From the start of treatment through 365 days (end of study)

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9010	9027		
Units: percentage of participants				
number (not applicable)	16.8	17.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With a Shift From Baseline to Worst Post-treatment Value in Clinical Laboratory Assessments

End point title	Number of Participants With a Shift From Baseline to Worst Post-treatment Value in Clinical Laboratory Assessments

End point description:

Clinical laboratory assessments included assessment of Hematology (hemoglobin, hematocrit, leukocytes and platelets) and Biochemistry (alkaline phosphatase [ALP], alanine aminotransferase [ALT], aspartate aminotransferase [AST], bilirubin and estimated glomerular filtration rate [eGFR]). Number of participants with shift from Baseline value to worst post-treatment value (low, normal, or high) was reported. Worst criterion for parameters is as follows: hematocrit - low, hemoglobin - low, leukocytes - high, platelets - low, ALT - high, ALP - high, AST - high, bilirubin - high, direct bilirubin - high, indirect bilirubin - high, eGFR - severe impairment. SAS comprised all participants in ITT Analysis set who received any amount of investigational product, and were analyzed based on actual treatment received. Here, number of participants analysed (N) = all participants who were evaluated for this endpoint."n" = participants who were evaluated for this endpoint for the specified category.

End point type	Secondary

End point timeframe:

Baseline and 29 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8372	8392		
Units: participants				
Hematocrit - High to Low (n=6848, 6810)	0	1		
Hematocrit - Normal to Low (n=6848, 6810)	365	393		
Hemoglobin - High to Low (n=7235,7185)	0	1		
Hemoglobin - Normal to Low (n=7235,7185)	457	447		
Leukocytes - Normal to High (n=7229,7184)	267	271		
Leukocytes - Low to High (n=7229,7184)	2	1		

Platelets - High to Low (n=7138,7064)	0	0		
Platelets - Normal to Low (n=7138,7064)	92	114		
ALT - Normal to High (n=7904,7949)	658	612		
ALT - Low to High (n=7904,7949)	0	0		
ALP - Normal to High (n=8341,8366)	307	350		
ALP - Low to High (n=8341,8366)	1	0		
AST - Normal to High (n=7910,7911)	239	253		
AST - Low to High (n=7910,7911)	2	0		
Bilirubin - Normal to High (n=8281,8284)	73	112		
Bilirubin - Low to High (n=8281,8284)	0	1		
Direct Bilirubin - Normal to High (n=7273,7317)	18	21		
Direct Bilirubin - Low to High (n=7273,7317)	0	0		
Indirect Bilirubin - Normal to High (n=7269,7309)	31	42		
Indirect Bilirubin - Low to High (n=7269,7309)	0	0		
eGFR - Normal to Severe (n=8372,8392)	1	2		
eGFR - Mild to Severe (n=8372,8392)	15	9		
eGFR - Moderate to Severe (n=8372,8392)	91	99		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Shift From Baseline to Worst Post-treatment Value in Clinical Laboratory Assessments

End point title	Percentage of Participants With a Shift From Baseline to Worst Post-treatment Value in Clinical Laboratory Assessments

End point description:

Clinical laboratory assessments included assessment of Hematology (hemoglobin, hematocrit, leukocytes and platelets) and Biochemistry (ALP, ALT, AST, bilirubin and eGFR). Percentage of participants with a shift from the Baseline value to the worst post-treatment value (low, normal, or high) was reported. The worst criterion for the parameters is as follows: hematocrit - low, hemoglobin - low, leukocytes - high, platelets - low, ALT - high, ALP - high, AST - high, bilirubin - high, direct bilirubin - high, indirect bilirubin - high, eGFR - severe impairment. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint and "n" included all participants who were evaluated for this endpoint for the specified category.

End point type	Secondary

End point timeframe:

Baseline and 29 days

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8372	8392		
Units: percentage of participants				
number (not applicable)				
Hematocrit - High to Low (n=6848, 6810)	0.0	0.0		
Hematocrit - Normal to Low (n=6848, 6810)	5.3	5.8		
Hemoglobin - High to Low (n=7235,7185)	0.0	0.0		
Hemoglobin - Normal to Low (n=7235,7185)	6.3	6.2		
Leukocytes - Normal to High (n=7229,7184)	3.7	3.8		
Leukocytes - Low to High (n=7229,7184)	0.0	0.0		
Platelets - High to Low (n=7138,7064)	0.0	0.0		
Platelets - Normal to Low (n=7138,7064)	1.3	1.6		
ALT - Normal to High (n=7904,7949)	8.3	7.7		
ALT - Low to High (n=7904,7949)	0.0	0.0		
ALP - Normal to High (n=8341,8366)	3.7	4.2		
ALP - Low to High (n=8341,8366)	0.0	0.0		
AST - Normal to High (n=7910,7911)	3.0	3.2		
AST - Low to High (n=7910,7911)	0.0	0.0		
Bilirubin - Normal to High (n=8281,8284)	0.9	1.4		
Bilirubin - Low to High (n=8281,8284)	0.0	0.0		
Direct Bilirubin - Normal to High (n=7273,7317)	0.2	0.3		
Direct Bilirubin - Low to High (n=7273,7317)	0.0	0.0		
Indirect Bilirubin - Normal to High (n=7269,7309)	0.4	0.6		
Indirect Bilirubin - Low to High (n=7269,7309)	0.0	0.0		
eGFR - Normal to Severe (n=8372,8392)	0.0	0.0		
eGFR - Mild to Severe (n=8372,8392)	0.2	0.1		
eGFR - Moderate to Severe (n=8372,8392)	1.1	1.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hematology Parameters

End point title	Change From Baseline in Hematology Parameters

End point description:

Hematology parameters included Basophils, Eosinophils, Leukocytes, Lymphocytes, Monocytes, Neutrophils and Platelets. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint and "n" included all participants who were evaluated for this

endpoint for the specified category.

End point type	Secondary
End point timeframe:	
From Baseline to Day 29	

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7073	7021		
Units: 10^9 cells per litre				
arithmetic mean (standard deviation)				
Basophils (n=7061,7011)	0.004 (± 0.0455)	0.005 (± 0.0462)		
Eosinophils (n=7061,7011)	0.045 (± 0.1766)	0.047 (± 0.1727)		
Leukocytes (n=7073,7021)	-1.024 (± 2.2905)	-0.969 (± 2.2683)		
Lymphocytes (n=7061,7011)	0.084 (± 0.5534)	0.080 (± 0.5409)		
Monocytes (n=7061,7011)	-0.089 (± 0.1886)	-0.087 (± 0.1961)		
Neutrophils (n=7061,7011)	-1.068 (± 2.0892)	-1.011 (± 2.0343)		
Platelets (n=6985,6908)	0.4 (± 56.09)	-1.4 (± 55.31)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hematology Parameter: Hematocrit

End point title	Change From Baseline in Hematology Parameter: Hematocrit

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint.

End point type	Secondary
End point timeframe:	
From Baseline to Day 29	

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6698	6651		
Units: litre per litre (L/L)				
arithmetic mean (standard deviation)	-0.003 (± 0.0382)	-0.004 (± 0.0381)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hematology Parameter: Hemoglobin

End point title	Change From Baseline in Hematology Parameter: Hemoglobin

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed included all participants who were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

From Baseline to Day 29

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7074	7021		
Units: grams per litre (g/L)				
arithmetic mean (standard deviation)	-1.1 (± 11.96)	-1.3 (± 12.08)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hepatic Parameters

End point title	Change From Baseline in Hepatic Parameters

End point description:

Hepatic parameters included ALT, ALP and AST. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint and "n" included all participants who were evaluated for this endpoint for the specified category.

End point type	Secondary

End point timeframe:

From Baseline to Day 29

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8079	8072		
Units: units per litre				
arithmetic mean (standard deviation)				
ALT (n=7628,7630)	-5.5 (± 25.52)	-6.5 (± 28.91)		
ALP (n=8079,8072)	3.2 (± 26.13)	4.5 (± 24.55)		
AST (n=7616,7574)	-21.2 (± 41.90)	-20.7 (± 61.63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hepatic Parameter: Bilirubin

End point title	Change From Baseline in Hepatic Parameter: Bilirubin

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint and "n" included all participants who were evaluated for this endpoint for the specified category.

End point type	Secondary

End point timeframe:

From Baseline to Day 29

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8005	7983		
Units: micromol per litre (umol/L)				
arithmetic mean (standard deviation)				
Bilirubin (n=8005,7983)	-2.6 (± 4.71)	-1.9 (± 5.05)		
Direct Bilirubin (n=6961,6958)	-0.4 (± 1.32)	-0.3 (± 1.75)		
Indirect Bilirubin (n=6957,6950)	-2.0 (± 3.85)	-1.4 (± 3.90)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Renal Parameter: Serum Creatinine

End point title	Change From Baseline in Renal Parameter: Serum Creatinine

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

From Baseline to Day 29

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8114	8101		
Units: umol/L				
arithmetic mean (standard deviation)	2.4 (± 24.39)	2.1 (± 21.23)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Renal Parameter: eGFR

End point title	Change From Baseline in Renal Parameter: eGFR

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

From Baseline to Day 29

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8112	8098		
Units: millilitre per minute per 1.73 meter^2				
arithmetic mean (standard deviation)	-1.3 (± 11.87)	-1.2 (± 12.15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Renal Parameter: Blood Urea Nitrogen

End point title	Change From Baseline in Renal Parameter: Blood Urea Nitrogen

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

From Baseline to Day 29

End point values	CSL112	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8114	8105		
Units: millimoles per litre				
arithmetic mean (standard deviation)	0.0 (± 2.76)	0.0 (± 2.67)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All AEs were collected through Day 90 and AEs related to the study drug, those leading to its discontinuation, withdrawal of consent, all-cause mortality and all SAEs were collected up to Day 365 (End of study).

Adverse event reporting additional description:

AE analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. All-cause mortality reported for ITT analysis set (N = 9112 for CSL112 and N= 9107 for Placebo).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	CSL112

Reporting group description:

Participants received 6 grams of CSL112 (apoA-I purified from human plasma) once weekly via IV infusion for up to 4 weeks.

Reporting group title	Placebo

Reporting group description:

Participants received placebo (25% albumin solution diluted to 4.4%) once weekly via IV infusion for up to 4 weeks.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: There were no non-serious adverse events above the threshold of 5%.

Serious adverse events	CSL112	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1514 / 9010 (16.80%)	1557 / 9027 (17.25%)	
number of deaths (all causes)	348	355	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	7 / 9010 (0.08%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	5 / 9010 (0.06%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 3	0 / 1	
Small cell lung cancer			

subjects affected / exposed	5 / 9010 (0.06%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 0	
Gastric cancer			
subjects affected / exposed	4 / 9010 (0.04%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Lung adenocarcinoma			
subjects affected / exposed	4 / 9010 (0.04%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Pancreatic carcinoma			
subjects affected / exposed	4 / 9010 (0.04%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Prostate cancer			
subjects affected / exposed	4 / 9010 (0.04%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal adenocarcinoma			
subjects affected / exposed	4 / 9010 (0.04%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myelodysplastic syndrome			
subjects affected / exposed	3 / 9010 (0.03%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			

subjects affected / exposed	3 / 9010 (0.03%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	2 / 9010 (0.02%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Small cell lung cancer metastatic			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant neoplasm of unknown primary site			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cancer metastatic			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Benign pancreatic neoplasm			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder papilloma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour pulmonary			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			

subjects affected / exposed	1 / 9010 (0.01%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder adenocarcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder neoplasm			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer stage 0			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal adenocarcinoma			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Glioblastoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma multiforme			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
subjects affected / exposed	1 / 9010 (0.01%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
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	1 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Lung squamous cell carcinoma stage IV			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant oligodendroglioma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone marrow			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to lung			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic uterine cancer			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neuroendocrine tumour			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma recurrent			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer metastatic			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic carcinoma metastatic			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pituitary tumour benign			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			

subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal cancer			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland neoplasm			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral cancer metastatic			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal adenoma			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma stage II			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Borderline mucinous tumour of ovary			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm benign			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cancer pain			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choroid melanoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ciliary body melanoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer metastatic			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer stage I			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stromal tumour			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal adenocarcinoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal papilloma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant melanoma			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant urinary tract neoplasm			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic renal cell carcinoma			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ovarian cancer stage III			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreatic carcinoma stage IV			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic neuroendocrine tumour			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage II			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of renal pelvis and ureter metastatic			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma recurrent			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour necrosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			

subjects affected / exposed	17 / 9010 (0.19%)	15 / 9027 (0.17%)	
occurrences causally related to treatment / all	0 / 19	2 / 15	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic aneurysm			
subjects affected / exposed	11 / 9010 (0.12%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 11	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	11 / 9010 (0.12%)	14 / 9027 (0.16%)	
occurrences causally related to treatment / all	0 / 11	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	10 / 9010 (0.11%)	12 / 9027 (0.13%)	
occurrences causally related to treatment / all	0 / 10	1 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	7 / 9010 (0.08%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	7 / 9010 (0.08%)	11 / 9027 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic stenosis			
subjects affected / exposed	4 / 9010 (0.04%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	4 / 9010 (0.04%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			

subjects affected / exposed	4 / 9010 (0.04%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	3 / 9010 (0.03%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	2 / 9010 (0.02%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	2 / 9010 (0.02%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	1 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	2 / 9010 (0.02%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiodysplasia			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic thrombosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			

subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dialysis hypotension			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granulomatosis with polyangiitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemodynamic instability			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	1 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			

subjects affected / exposed	1 / 9010 (0.01%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Iliac artery stenosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoedema			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accelerated hypertension			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial occlusive disease			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial rupture			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic vascular disorder			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leriche syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Raynaud's phenomenon			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Assisted suicide			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	92 / 9010 (1.02%)	78 / 9027 (0.86%)	
occurrences causally related to treatment / all	0 / 97	1 / 99	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	12 / 9010 (0.13%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	1 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	7 / 9010 (0.08%)	15 / 9027 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	

Vascular stent stenosis			
subjects affected / exposed	7 / 9010 (0.08%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	5 / 9010 (0.06%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Gait disturbance			
subjects affected / exposed	4 / 9010 (0.04%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	3 / 9010 (0.03%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Medical device site haematoma			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Drowning			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Impaired healing			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion site reaction			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adverse drug reaction			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	0 / 9010 (0.00%)	10 / 9027 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug intolerance			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			

subjects affected / exposed	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated polyserositis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Physical deconditioning			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sudden death			

subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Vascular stent thrombosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	5 / 9010 (0.06%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	4 / 5	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	4 / 9010 (0.04%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytokine storm			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Loss of personal independence in daily activities			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Victim of abuse			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Physical disability			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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			
Prostatitis			
subjects affected / exposed	3 / 9010 (0.03%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic haemorrhage			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular pain			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic haematoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic pain			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Prostatic disorder			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	21 / 9010 (0.23%)	29 / 9027 (0.32%)	
occurrences causally related to treatment / all	0 / 28	0 / 41	
deaths causally related to treatment / all	0 / 2	0 / 0	
Dyspnoea			
subjects affected / exposed	17 / 9010 (0.19%)	13 / 9027 (0.14%)	
occurrences causally related to treatment / all	2 / 17	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	14 / 9010 (0.16%)	12 / 9027 (0.13%)	
occurrences causally related to treatment / all	0 / 14	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 1	
Respiratory failure			
subjects affected / exposed	10 / 9010 (0.11%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 1	
Epistaxis			
subjects affected / exposed	8 / 9010 (0.09%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pleural effusion			
subjects affected / exposed	8 / 9010 (0.09%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	7 / 9010 (0.08%)	11 / 9027 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	5 / 9010 (0.06%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Asthma			
subjects affected / exposed	4 / 9010 (0.04%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	4 / 9010 (0.04%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			

subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary congestion			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	2 / 9010 (0.02%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 2	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aspiration			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthma-chronic obstructive pulmonary disease overlap syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthmatic crisis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic abnormal relaxation			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea at rest			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 9010 (0.01%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Laryngeal oedema			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rales			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal fistula			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alveolar proteinosis			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinal haematoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthopnoea			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary fibrosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis allergic			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheomalacia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic wound			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Delirium			
subjects affected / exposed	3 / 9010 (0.03%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			

subjects affected / exposed	2 / 9010 (0.02%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tobacco withdrawal symptoms			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjustment disorder with depressed mood			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder due to a general medical condition			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Depression			
subjects affected / exposed	0 / 9010 (0.00%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed anxiety and depressive disorder			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device occlusion			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	18 / 9010 (0.20%)	12 / 9027 (0.13%)	
occurrences causally related to treatment / all	0 / 19	1 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	11 / 9010 (0.12%)	17 / 9027 (0.19%)	
occurrences causally related to treatment / all	0 / 11	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	7 / 9010 (0.08%)	12 / 9027 (0.13%)	
occurrences causally related to treatment / all	2 / 7	4 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	6 / 9010 (0.07%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	4 / 9010 (0.04%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			

subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder rupture			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic steatosis			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dyskinesia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary obstruction			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis obstructive			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic fibrosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis cholestatic			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 9010 (0.00%)	4 / 9027 (0.04%)	
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 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic function abnormal			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Troponin increased			
subjects affected / exposed	5 / 9010 (0.06%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	4 / 9010 (0.04%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	2 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			

subjects affected / exposed	2 / 9010 (0.02%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza A virus test positive			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level abnormal			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial test positive			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood magnesium decreased			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium increased			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerular filtration rate decreased			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory marker increased			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Occult blood positive			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I increased			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiogram peripheral abnormal			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium decreased			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Blood urine present				
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Gram stain positive				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
International normalised ratio increased				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Pulmonary arterial pressure increased				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Staphylococcus test positive				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Troponin T increased				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
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	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	11 / 9010 (0.12%)	11 / 9027 (0.12%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	9 / 9010 (0.10%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	8 / 9010 (0.09%)	11 / 9027 (0.12%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Head injury			
subjects affected / exposed	6 / 9010 (0.07%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hip fracture			
subjects affected / exposed	6 / 9010 (0.07%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	5 / 9010 (0.06%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprocedural myocardial infarction			
subjects affected / exposed	4 / 9010 (0.04%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			

subjects affected / exposed	4 / 9010 (0.04%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site haematoma			
subjects affected / exposed	3 / 9010 (0.03%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac procedure complication			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniofacial fracture			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			

subjects affected / exposed	2 / 9010 (0.02%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	2 / 9010 (0.02%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pneumothorax			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vascular access site haemorrhage			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic leak			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal injury			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal injury			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back injury			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemical burns of eye			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eschar			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exposure to SARS-CoV-2			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural haematoma			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face injury			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal anastomotic leak			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural myocardial infarction			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thoracic procedure complication			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thrombosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postpericardiotomy syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal transplant failure			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory fume inhalation disorder			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			

subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth fracture			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic renal injury			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention postoperative			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular injury			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal injury			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachial plexus injury			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	0 / 9010 (0.00%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gas poisoning			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Gastrointestinal anastomotic haemorrhage				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Hyphaema				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Intervertebral disc injury				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Jaw fracture				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Lower limb fracture				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Lumbar vertebral fracture				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Post procedural complication circulatory				
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Post procedural haematoma				

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural hypotension			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural dizziness			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation proctitis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract procedural complication			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Road traffic accident			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal haematoma			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic arthritis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site dissection			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphatic malformation			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	106 / 9010 (1.18%)	84 / 9027 (0.93%)	
occurrences causally related to treatment / all	0 / 107	0 / 89	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	69 / 9010 (0.77%)	59 / 9027 (0.65%)	
occurrences causally related to treatment / all	0 / 73	0 / 63	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac failure			
subjects affected / exposed	54 / 9010 (0.60%)	64 / 9027 (0.71%)	
occurrences causally related to treatment / all	0 / 61	2 / 67	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	48 / 9010 (0.53%)	48 / 9027 (0.53%)	
occurrences causally related to treatment / all	0 / 50	0 / 53	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	23 / 9010 (0.26%)	27 / 9027 (0.30%)	
occurrences causally related to treatment / all	0 / 23	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	20 / 9010 (0.22%)	21 / 9027 (0.23%)	
occurrences causally related to treatment / all	1 / 21	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	19 / 9010 (0.21%)	29 / 9027 (0.32%)	
occurrences causally related to treatment / all	0 / 19	0 / 29	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	14 / 9010 (0.16%)	16 / 9027 (0.18%)	
occurrences causally related to treatment / all	0 / 15	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocardial ischaemia			
subjects affected / exposed	14 / 9010 (0.16%)	19 / 9027 (0.21%)	
occurrences causally related to treatment / all	0 / 15	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	14 / 9010 (0.16%)	23 / 9027 (0.25%)	
occurrences causally related to treatment / all	0 / 14	0 / 24	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrial flutter			

subjects affected / exposed	12 / 9010 (0.13%)	15 / 9027 (0.17%)	
occurrences causally related to treatment / all	0 / 12	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	11 / 9010 (0.12%)	13 / 9027 (0.14%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 2	0 / 3	
Pericarditis			
subjects affected / exposed	10 / 9010 (0.11%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock			
subjects affected / exposed	10 / 9010 (0.11%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 10	1 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	9 / 9010 (0.10%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	8 / 9010 (0.09%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	8 / 9010 (0.09%)	10 / 9027 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	8 / 9010 (0.09%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			

subjects affected / exposed	7 / 9010 (0.08%)	12 / 9027 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	7 / 9010 (0.08%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 8	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	7 / 9010 (0.08%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	1 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	7 / 9010 (0.08%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	5 / 9010 (0.06%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	5 / 9010 (0.06%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	5 / 9010 (0.06%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	5 / 9010 (0.06%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes			

subjects affected / exposed	4 / 9010 (0.04%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	4 / 9010 (0.04%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	4 / 9010 (0.04%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dressler's syndrome			
subjects affected / exposed	4 / 9010 (0.04%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	4 / 9010 (0.04%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postinfarction angina			
subjects affected / exposed	4 / 9010 (0.04%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	4 / 9010 (0.04%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	3 / 9010 (0.03%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure chronic			

subjects affected / exposed	3 / 9010 (0.03%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery perforation			
subjects affected / exposed	3 / 9010 (0.03%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	2 / 9010 (0.02%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	2 / 9010 (0.02%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ventricular thrombosis			
subjects affected / exposed	2 / 9010 (0.02%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve stenosis			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial injury			

subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	2 / 9010 (0.02%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus arrest			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia supraventricular			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriospasm coronary			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac asthma			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac discomfort			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic coronary syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery dissection			
subjects affected / exposed	1 / 9010 (0.01%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery insufficiency			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Low cardiac output syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial rupture			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal rhythm			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial haemorrhage			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prinzmetal angina			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	1 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anginal equivalent			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac dysfunction			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiorenal syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			

subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac thrombus			
subjects affected / exposed	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial mass			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trifascicular block			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricle rupture			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Syncope			
subjects affected / exposed	23 / 9010 (0.26%)	26 / 9027 (0.29%)	
occurrences causally related to treatment / all	0 / 24	0 / 26	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			

subjects affected / exposed	6 / 9010 (0.07%)	10 / 9027 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	5 / 9010 (0.06%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	5 / 9010 (0.06%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	5 / 9010 (0.06%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	5 / 9010 (0.06%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	4 / 9010 (0.04%)	10 / 9027 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	3 / 9010 (0.03%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epilepsy			
subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			

subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular disorder			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (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 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	2 / 9010 (0.02%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neuralgia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinsonism			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Amnesia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia haemorrhage			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid sinus syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery stenosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cerebral ischaemia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebrovascular insufficiency			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic coma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness postural			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic transformation stroke			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic encephalopathy			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoparesis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudoradicular syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paralysis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery aneurysm			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral atrophy			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral thrombosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dystonia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restless legs syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery stenosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	40 / 9010 (0.44%)	39 / 9027 (0.43%)	
occurrences causally related to treatment / all	0 / 45	1 / 43	
deaths causally related to treatment / all	0 / 0	0 / 1	
Iron deficiency anaemia			
subjects affected / exposed	9 / 9010 (0.10%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	3 / 9010 (0.03%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymph node pain			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			

subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
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 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired haemophilia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia macrocytic			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic disorder			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo positional			

subjects affected / exposed	4 / 9010 (0.04%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	0 / 9010 (0.00%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract nuclear			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye allergy			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy hypertensive			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacrimation increased			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Purtscher retinopathy			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tolosa-Hunt syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	13 / 9010 (0.14%)	19 / 9027 (0.21%)	
occurrences causally related to treatment / all	0 / 14	0 / 19	
deaths causally related to treatment / all	0 / 1	0 / 1	
Gastritis			
subjects affected / exposed	10 / 9010 (0.11%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	8 / 9010 (0.09%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	7 / 9010 (0.08%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	7 / 9010 (0.08%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	7 / 9010 (0.08%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	6 / 9010 (0.07%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	6 / 9010 (0.07%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	6 / 9010 (0.07%)	12 / 9027 (0.13%)	
occurrences causally related to treatment / all	1 / 6	2 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	5 / 9010 (0.06%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	5 / 9010 (0.06%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			

subjects affected / exposed	5 / 9010 (0.06%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	4 / 9010 (0.04%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	4 / 9010 (0.04%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	0 / 4	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	4 / 9010 (0.04%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	4 / 9010 (0.04%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatitis			
subjects affected / exposed	4 / 9010 (0.04%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	3 / 9010 (0.03%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal polyp haemorrhage			
subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			

subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Ileus			
subjects affected / exposed	3 / 9010 (0.03%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	3 / 9010 (0.03%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			

subjects affected / exposed	2 / 9010 (0.02%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival bleeding			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	2 / 9010 (0.02%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal stenosis			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vomiting			

subjects affected / exposed	2 / 9010 (0.02%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	1 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphthous ulcer			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental caries			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric antral vascular ectasia			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal pain			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal polyp			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal vascular malformation haemorrhagic			

subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic erosive gastritis			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heyde's syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal pseudo-obstruction			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mouth haemorrhage			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	1 / 9010 (0.01%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer haemorrhage			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis haemorrhagic			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Peptic ulcer			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertensive gastropathy			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute abdomen			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastroparesis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea haemorrhagic			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis haemorrhagic			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocutaneous fistula			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric polyps			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal erosion			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal obstruction			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal toxicity			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhoids			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical ileus			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery stenosis			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Noninfective sialoadenitis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 9010 (0.00%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic atrophy			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis relapsing			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reflux gastritis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			

subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 9010 (0.00%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	8 / 9010 (0.09%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	1 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dermal cyst			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotic angiodermatitis			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panniculitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis contact			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug eruption			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ingrowing nail			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash pruritic			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	68 / 9010 (0.75%)	66 / 9027 (0.73%)	
occurrences causally related to treatment / all	10 / 72	5 / 71	
deaths causally related to treatment / all	0 / 2	0 / 0	
Renal impairment			
subjects affected / exposed	15 / 9010 (0.17%)	14 / 9027 (0.16%)	
occurrences causally related to treatment / all	2 / 15	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	14 / 9010 (0.16%)	10 / 9027 (0.11%)	
occurrences causally related to treatment / all	0 / 16	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	12 / 9010 (0.13%)	14 / 9027 (0.16%)	
occurrences causally related to treatment / all	1 / 13	1 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy toxic			
subjects affected / exposed	11 / 9010 (0.12%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	10 / 9010 (0.11%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			

subjects affected / exposed	6 / 9010 (0.07%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	4 / 9010 (0.04%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 4	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	4 / 9010 (0.04%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal injury			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder disorder			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelocaliectasis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral haemorrhage			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder diverticulum			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder tamponade			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urethral			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis erosive			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage urinary tract			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic bladder			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal infarct			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal salt-wasting syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vesical fistula			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaldosteronism			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenocortical insufficiency acute			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Bladder transitional cell carcinoma			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic squamous cell carcinoma			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paget's disease of nipple			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal neoplasm			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypopharyngeal cancer recurrent			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	8 / 9010 (0.09%)	15 / 9027 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			

subjects affected / exposed	6 / 9010 (0.07%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	5 / 9010 (0.06%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	5 / 9010 (0.06%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	4 / 9010 (0.04%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	4 / 9010 (0.04%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	3 / 9010 (0.03%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	3 / 9010 (0.03%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	3 / 9010 (0.03%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			

subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma muscle			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc space narrowing			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue necrosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle haemorrhage			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal synovial cyst			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			

subjects affected / exposed	97 / 9010 (1.08%)	89 / 9027 (0.99%)	
occurrences causally related to treatment / all	0 / 99	0 / 93	
deaths causally related to treatment / all	0 / 4	0 / 3	
COVID-19 pneumonia			
subjects affected / exposed	52 / 9010 (0.58%)	46 / 9027 (0.51%)	
occurrences causally related to treatment / all	0 / 52	0 / 47	
deaths causally related to treatment / all	0 / 13	0 / 12	
COVID-19			
subjects affected / exposed	42 / 9010 (0.47%)	48 / 9027 (0.53%)	
occurrences causally related to treatment / all	0 / 42	0 / 49	
deaths causally related to treatment / all	0 / 10	0 / 8	
Urinary tract infection			
subjects affected / exposed	37 / 9010 (0.41%)	36 / 9027 (0.40%)	
occurrences causally related to treatment / all	0 / 38	1 / 39	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	26 / 9010 (0.29%)	26 / 9027 (0.29%)	
occurrences causally related to treatment / all	0 / 26	0 / 26	
deaths causally related to treatment / all	0 / 3	0 / 5	
Urosepsis			
subjects affected / exposed	12 / 9010 (0.13%)	8 / 9027 (0.09%)	
occurrences causally related to treatment / all	0 / 13	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Gastroenteritis			
subjects affected / exposed	12 / 9010 (0.13%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cellulitis			
subjects affected / exposed	9 / 9010 (0.10%)	17 / 9027 (0.19%)	
occurrences causally related to treatment / all	0 / 9	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			

subjects affected / exposed	7 / 9010 (0.08%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	7 / 9010 (0.08%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	7 / 9010 (0.08%)	23 / 9027 (0.25%)	
occurrences causally related to treatment / all	0 / 7	0 / 23	
deaths causally related to treatment / all	0 / 3	0 / 12	
Osteomyelitis			
subjects affected / exposed	6 / 9010 (0.07%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	5 / 9010 (0.06%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	5 / 9010 (0.06%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	5 / 9010 (0.06%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pyelonephritis			
subjects affected / exposed	5 / 9010 (0.06%)	5 / 9027 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			

subjects affected / exposed	5 / 9010 (0.06%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	4 / 9010 (0.04%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	4 / 9010 (0.04%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diverticulitis			
subjects affected / exposed	3 / 9010 (0.03%)	7 / 9027 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	3 / 9010 (0.03%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Staphylococcal bacteraemia			
subjects affected / exposed	3 / 9010 (0.03%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			

subjects affected / exposed	2 / 9010 (0.02%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	2 / 9010 (0.02%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	2 / 9010 (0.02%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			

subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic herpes zoster			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parapharyngeal space infection			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	2 / 9010 (0.02%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed	2 / 9010 (0.02%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	2 / 9010 (0.02%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			

subjects affected / exposed	1 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acarodermatitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortitis syphilitic			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Babesiosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chikungunya virus infection			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complicated appendicitis			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus pneumonia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			

subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related sepsis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysematous cystitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal bacteraemia			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal sepsis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia pyelonephritis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis bacterial			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin infection			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter infection			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis E			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Klebsiella urinary tract infection			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site infection			
subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site joint infection			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle abscess			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pseudomonal			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			

subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory tract infection bacterial			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonella sepsis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis septic			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			

subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection enterococcal			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site infection			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (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	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			

subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial prostatitis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Citrobacter sepsis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis klebsiella			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus colitis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis enterococcal			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter pneumonia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelothrix sepsis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gas gangrene			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Giardiasis			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter gastritis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis B			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster disseminated			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 9010 (0.00%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella bacteraemia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal abscess			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia acinetobacter			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia legionella			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyoderma			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyonephrosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyuria			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal abscess			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strongyloidiasis			

subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	12 / 9010 (0.13%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 14	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hyperglycaemia			
subjects affected / exposed	10 / 9010 (0.11%)	14 / 9027 (0.16%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	9 / 9010 (0.10%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	7 / 9010 (0.08%)	6 / 9027 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			

subjects affected / exposed	5 / 9010 (0.06%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	4 / 9010 (0.04%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	4 / 9010 (0.04%)	9 / 9027 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	3 / 9010 (0.03%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	2 / 9010 (0.02%)	4 / 9027 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abnormal loss of weight			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic metabolic decompensation			

subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Euglycaemic diabetic ketoacidosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperinsulinaemic hypoglycaemia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	1 / 9010 (0.01%)	3 / 9027 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 9010 (0.01%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	1 / 9010 (0.01%)	0 / 9027 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			

subjects affected / exposed	1 / 9010 (0.01%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	0 / 9010 (0.00%)	2 / 9027 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypernatraemia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophosphataemia			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
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	0 / 9010 (0.00%)	1 / 9027 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	CSL112	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 9010 (0.00%)	0 / 9027 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 September 2019	The list below describes key changes to the Clinical Study Protocol: • Modified the primary endpoint to include all MI events instead of only type 1 (spontaneous) MI events. • In the original protocol (dated 23 January 2018) for Inclusion Criteria 6, participants were required to have at least 1 of the following established risk factors: age >= 65 years, prior history of MI, diabetes mellitus requiring pharmacotherapy, or peripheral artery disease. Modification of Inclusion Criteria 6 utilized the same risk factors but instead required the presence of diabetes mellitus requiring pharmacotherapy, or 2 or more of the following: age >= 65 years, prior history of MI, and peripheral artery disease. This modification to Inclusion Criteria 6 was implemented to limit enrollment to participants that were at an even higher risk of an early recurrent cardiovascular event. • Included additional secondary and exploratory endpoints. • Specified that the 70% interim analysis would not be performed if the expected IDMC review of the interim analysis was less than 2 months prior to the anticipated completion of enrollment. • Included the option to limit the number of participants enrolled with a specific index MI type (ie, STEMI or NSTEMI). • Added updated nonclinical data as well as clinical data from Study CSL112_1002. • Modified wording to provide clarifications and improve protocol compliance.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported