



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
Global end of trial date	GR HR IT RO 17 November 2023

Results information

Result version number	v2 (current)
This version publication date	13 February 2025
First version publication date	20 October 2024

Version creation reason	<ul style="list-style-type: none">• Correction of full data set Minor updates have been made to align the results posting with the study's clinicaltrials.gov results record.
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Trial information

Trial identification

Sponsor protocol code	CSL112_3001
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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	Chile: 53
Country: Number of subjects enrolled	Colombia: 137
Country: Number of subjects enrolled	Malaysia: 278
Country: Number of subjects enrolled	New Zealand: 101
Country: Number of subjects enrolled	Peru: 14
Country: Number of subjects enrolled	Singapore: 39
Country: Number of subjects enrolled	United Kingdom: 99
Country: Number of subjects enrolled	United States: 1845

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	Croatia: 40
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	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	Türkiye: 450
Country: Number of subjects enrolled	Switzerland: 172
Country: Number of subjects enrolled	Ukraine: 734
Country: Number of subjects enrolled	Hong Kong: 35
Country: Number of subjects enrolled	Taiwan: 194
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	Georgia: 178
Country: Number of subjects enrolled	Israel: 1015
Country: Number of subjects enrolled	Japan: 322
Country: Number of subjects enrolled	Korea, Republic of: 194
Country: Number of subjects enrolled	Mexico: 283
Country: Number of subjects enrolled	Russian Federation: 878
Country: Number of subjects enrolled	Serbia: 511
Country: Number of subjects enrolled	South Africa: 100
Country: Number of subjects enrolled	Thailand: 281
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 per sponsor decision. Intent-to-treat population used for disposition.

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
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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
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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
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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 standard deviation	65.6 ± 10.09	65.4 ± 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 7 participants enrolled at site(s) excluded from analysis per sponsor decision. 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
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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 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary
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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
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End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary
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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,
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End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. 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 7 participants enrolled at site(s) excluded from analysis per sponsor decision. 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 7 participants enrolled at site(s) excluded from analysis per sponsor decision. 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 7 participants enrolled at site(s) excluded from analysis per sponsor decision. 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
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End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary
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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
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End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

End point type	Secondary
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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
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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
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End point timeframe:

From the start of treatment through 379 days (Day 365 + 14 days of follow up)

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
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End point description:

Treatment-related AEs were AEs considered by the Investigator to have a causal relationship to the investigational product. As per the study statistical analysis plan (SAP), descriptive percentages were displayed to one decimal place, hence the percentage values were rounded off and presented. 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
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End point timeframe:

From the start of treatment through 379 days (Day 365 + 14 days of follow up)

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 379 days (Day 365 + 14 days of follow up)			

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. As per the SAP, descriptive percentages were displayed to one decimal place, hence the percentage values were rounded off and presented. 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 379 days (Day 365 + 14 days of follow up)	

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
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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
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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
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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 (\pm 0.0382)	-0.004 (\pm 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
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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
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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 (\pm 11.96)	-1.3 (\pm 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
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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
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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
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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
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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
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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 study drug, those leading to its discontinuation, withdrawal of consent, all-cause mortality, Other AEs and all SAEs were collected up to Day 379 (Day 365+ 14 days of follow-up)

Adverse event reporting additional description:

All-cause mortality was monitored/assessed for the ITT population (N = 9112 for CSL112 and N= 9107 for Placebo), but Serious and Other AEs were only monitored/assessed for the SAS population. SAS was the primary population for summarizing and reporting safety data (SAEs and Other AEs).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	Placebo
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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 title	CSL112
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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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Vascular stent stenosis			
subjects affected / exposed	6 / 9027 (0.07%)	7 / 9010 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 9027 (0.01%)	5 / 9010 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 2	
Gait disturbance			
subjects affected / exposed	2 / 9027 (0.02%)	4 / 9010 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	2 / 9027 (0.02%)	3 / 9010 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Medical device site haematoma			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	2 / 9027 (0.02%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Drowning			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Impaired healing			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adverse drug reaction			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	10 / 9027 (0.11%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 10	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug intolerance			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			

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

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

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

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

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

subjects affected / exposed	2 / 9027 (0.02%)	2 / 9010 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary congestion			
subjects affected / exposed	2 / 9027 (0.02%)	2 / 9010 (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	1 / 9027 (0.01%)	2 / 9010 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	7 / 9027 (0.08%)	2 / 9010 (0.02%)	
occurrences causally related to treatment / all	1 / 7	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aspiration			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthma-chronic obstructive pulmonary disease overlap syndrome			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthmatic crisis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea at rest			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	4 / 9027 (0.04%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	3 / 9027 (0.03%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Laryngeal oedema			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			

subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rales			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alveolar proteinosis			

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

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

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

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

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

subjects affected / exposed	0 / 9027 (0.00%)	2 / 9010 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder rupture			
subjects affected / exposed	2 / 9027 (0.02%)	2 / 9010 (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	0 / 9027 (0.00%)	2 / 9010 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	0 / 9027 (0.00%)	2 / 9010 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dyskinesia			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary obstruction			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic fibrosis		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis cholestatic		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary colic		
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	4 / 9027 (0.04%)	0 / 9010 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic function abnormal		

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

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

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

subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood urine present			
subjects affected / exposed	2 / 9027 (0.02%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gram stain positive			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial pressure increased			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcus test positive			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin T increased			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			

subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	11 / 9027 (0.12%)	11 / 9010 (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	6 / 9027 (0.07%)	9 / 9010 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	11 / 9027 (0.12%)	8 / 9010 (0.09%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Head injury			
subjects affected / exposed	4 / 9027 (0.04%)	6 / 9010 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hip fracture			
subjects affected / exposed	4 / 9027 (0.04%)	6 / 9010 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	7 / 9027 (0.08%)	5 / 9010 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprocedural myocardial infarction			
subjects affected / exposed	4 / 9027 (0.04%)	4 / 9010 (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	3 / 9027 (0.03%)	4 / 9010 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	1 / 9027 (0.01%)	3 / 9010 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	1 / 9027 (0.01%)	3 / 9010 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site haematoma			
subjects affected / exposed	2 / 9027 (0.02%)	3 / 9010 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac procedure complication			
subjects affected / exposed	1 / 9027 (0.01%)	2 / 9010 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniofacial fracture			
subjects affected / exposed	2 / 9027 (0.02%)	2 / 9010 (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 / 9027 (0.02%)	2 / 9010 (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	0 / 9027 (0.00%)	2 / 9010 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			

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

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

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

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

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

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

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

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

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

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

subjects affected / exposed	15 / 9027 (0.17%)	12 / 9010 (0.13%)
occurrences causally related to treatment / all	0 / 16	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	13 / 9027 (0.14%)	11 / 9010 (0.12%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 3	0 / 2
Pericarditis		
subjects affected / exposed	6 / 9027 (0.07%)	10 / 9010 (0.11%)
occurrences causally related to treatment / all	0 / 6	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	6 / 9027 (0.07%)	10 / 9010 (0.11%)
occurrences causally related to treatment / all	1 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Coronary artery stenosis		
subjects affected / exposed	7 / 9027 (0.08%)	9 / 9010 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Acute coronary syndrome		
subjects affected / exposed	6 / 9027 (0.07%)	8 / 9010 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	10 / 9027 (0.11%)	8 / 9010 (0.09%)
occurrences causally related to treatment / all	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	8 / 9027 (0.09%)	8 / 9010 (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	12 / 9027 (0.13%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	5 / 9027 (0.06%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	1 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	4 / 9027 (0.04%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	0 / 4	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	8 / 9027 (0.09%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	5 / 9027 (0.06%)	5 / 9010 (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	4 / 9027 (0.04%)	5 / 9010 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	4 / 9027 (0.04%)	5 / 9010 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular fibrillation		
subjects affected / exposed	6 / 9027 (0.07%)	5 / 9010 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Torsade de pointes		

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

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

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

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

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

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

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

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

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

subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinsonism			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Amnesia			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia haemorrhage			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid sinus syndrome			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery stenosis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			

subjects affected / exposed	4 / 9027 (0.04%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cerebral ischaemia			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic coma			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness postural			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic encephalopathy			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoparesis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post stroke epilepsy			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudoradicular syndrome			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			

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

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

subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restless legs syndrome			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery stenosis			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	39 / 9027 (0.43%)	40 / 9010 (0.44%)
occurrences causally related to treatment / all	1 / 43	0 / 45
deaths causally related to treatment / all	0 / 1	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	8 / 9027 (0.09%)	9 / 9010 (0.10%)
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	0 / 9027 (0.00%)	3 / 9010 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombocytopenia		
subjects affected / exposed	2 / 9027 (0.02%)	2 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normocytic anaemia		

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

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

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

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

subjects affected / exposed	3 / 9027 (0.03%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	3 / 9027 (0.03%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	4 / 9027 (0.04%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Rectal haemorrhage		
subjects affected / exposed	5 / 9027 (0.06%)	6 / 9010 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	7 / 9027 (0.08%)	6 / 9010 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	12 / 9027 (0.13%)	6 / 9010 (0.07%)
occurrences causally related to treatment / all	2 / 15	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	2 / 9027 (0.02%)	5 / 9010 (0.06%)
occurrences causally related to treatment / all	0 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	5 / 9027 (0.06%)	5 / 9010 (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	6 / 9027 (0.07%)	5 / 9010 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	3 / 9027 (0.03%)	4 / 9010 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	8 / 9027 (0.09%)	4 / 9010 (0.04%)
occurrences causally related to treatment / all	1 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	3 / 9027 (0.03%)	4 / 9010 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	2 / 9027 (0.02%)	4 / 9010 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatitis		
subjects affected / exposed	5 / 9027 (0.06%)	4 / 9010 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	5 / 9027 (0.06%)	3 / 9010 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal polyp haemorrhage		
subjects affected / exposed	1 / 9027 (0.01%)	3 / 9010 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		

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

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

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

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

subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal haemorrhage			

subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer haemorrhage		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Mouth haemorrhage		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	5 / 9027 (0.06%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer haemorrhage		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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 / 9027 (0.01%)	1 / 9010 (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 / 9027 (0.01%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Peptic ulcer		

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

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

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

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

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

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

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

subjects affected / exposed	8 / 9027 (0.09%)	6 / 9010 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	4 / 9027 (0.04%)	4 / 9010 (0.04%)
occurrences causally related to treatment / all	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	2 / 9027 (0.02%)	4 / 9010 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	1 / 9027 (0.01%)	3 / 9010 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	0 / 9027 (0.00%)	2 / 9010 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal injury		
subjects affected / exposed	0 / 9027 (0.00%)	2 / 9010 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder disorder		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus bladder		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		

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

subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal infarct			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal salt-wasting syndrome			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vesical fistula			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoadosteronism			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Bladder transitional cell carcinoma			
subjects affected / exposed	2 / 9027 (0.02%)	2 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paget's disease of nipple			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal neoplasm			
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypopharyngeal cancer recurrent			
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	15 / 9027 (0.17%)	8 / 9010 (0.09%)	
occurrences causally related to treatment / all	0 / 16	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			

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

subjects affected / exposed	1 / 9027 (0.01%)	2 / 9010 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma muscle			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc space narrowing			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			

subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue necrosis		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral foraminal stenosis		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chondrocalcinosis		
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Flank pain		
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint effusion		
subjects affected / exposed	1 / 9027 (0.01%)	0 / 9010 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle haemorrhage		

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

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

subjects affected / exposed	6 / 9027 (0.07%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	2 / 9027 (0.02%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	23 / 9027 (0.25%)	7 / 9010 (0.08%)
occurrences causally related to treatment / all	0 / 23	0 / 7
deaths causally related to treatment / all	0 / 12	0 / 3
Osteomyelitis		
subjects affected / exposed	7 / 9027 (0.08%)	6 / 9010 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	7 / 9027 (0.08%)	5 / 9010 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	0 / 9027 (0.00%)	5 / 9010 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	4 / 9027 (0.04%)	5 / 9010 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Pyelonephritis		
subjects affected / exposed	5 / 9027 (0.06%)	5 / 9010 (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	4 / 9027 (0.04%)	5 / 9010 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	6 / 9027 (0.07%)	4 / 9010 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia bacterial		
subjects affected / exposed	1 / 9027 (0.01%)	4 / 9010 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Diverticulitis		
subjects affected / exposed	7 / 9027 (0.08%)	3 / 9010 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	1 / 9027 (0.01%)	3 / 9010 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	3 / 9027 (0.03%)	3 / 9010 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	2 / 9027 (0.02%)	3 / 9010 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	2 / 9027 (0.02%)	2 / 9010 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		

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

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

subjects affected / exposed	3 / 9027 (0.03%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Acarodermatitis		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		
subjects affected / exposed	2 / 9027 (0.02%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		

subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary sepsis		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis infective		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chikungunya virus infection		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complicated appendicitis		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		

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

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

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

subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic abscess		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pseudomonal		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	1 / 9027 (0.01%)	1 / 9010 (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 / 9027 (0.01%)	1 / 9010 (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	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonella sepsis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternitis			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis septic			
subjects affected / exposed	0 / 9027 (0.00%)	1 / 9010 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			

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

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

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

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

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

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

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

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

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

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

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 September 2019	<p>The list below describes key changes to the Clinical Study Protocol:</p> <ul style="list-style-type: none">• 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 \geq 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 \geq 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