Clinical trial results:
A Phase 3 Randomized Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants with Severe COVID-19

Summary

EudraCT number	2020-000841-15
Trial protocol	DE ES FR IT NL GB SE
Global end of trial date	30 June 2020

Results information

Result version number	v1 (current)
This version publication date	31 December 2020
First version publication date	31 December 2020

Trial information

Trial identification

Sponsor protocol code	GS-US-540-5773

Additional study identifiers

ISRCTN number	ISRCTN15874265
ClinicalTrials.gov id (NCT number)	NCT04292899
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences
Sponsor organisation address	333 Lakeside Drive, Foster City, CA, United States, 94404
Public contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com
Scientific contact	Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 June 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 April 2020
Global end of trial reached?	Yes
Global end of trial date	30 June 2020
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 2 remdesivir (RDV) regimens with respect to clinical status assessed by a 7-point ordinal scale on Day 14.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 March 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 3917
Country: Number of subjects enrolled	Spain: 225
Country: Number of subjects enrolled	Italy: 203
Country: Number of subjects enrolled	United Kingdom: 183
Country: Number of subjects enrolled	Sweden: 89
Country: Number of subjects enrolled	Singapore: 60
Country: Number of subjects enrolled	Switzerland: 59
Country: Number of subjects enrolled	Netherlands: 47
Country: Number of subjects enrolled	Germany: 43
Country: Number of subjects enrolled	France: 27
Country: Number of subjects enrolled	Korea, Republic of: 22
Country: Number of subjects enrolled	Hong Kong: 6
Country: Number of subjects enrolled	Japan: 5
Country: Number of subjects enrolled	Taiwan: 5
Worldwide total number of subjects	4891
EEA total number of subjects	817

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	12
Adults (18-64 years)	3232
From 65 to 84 years	1525
85 years and over	122

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in the United States, Europe, and Asia. The first participant was screened on 06 March 2020. The last study visit occurred on 30 June 2020.

Pre-assignment

Screening details:

4958 participants were screened. 4891 participants were enrolled. 4 participants in Part A and 49 participants in Part B did not receive treatment and are not included in the analyses.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: Remdesivir (RDV) for 5 Days

Arm description:

Participants received continued standard of care (SOC) therapy together with intravenous (IV) RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-5.

Arm type	Experimental
Investigational medicinal product name	Remdesivir
Investigational medicinal product code	
Other name	GS-5734™, Veklury®
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered on Day 1 followed by 100 mg on Days 2-5.

Investigational medicinal product name	Standard of care
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Not mentioned

Dosage and administration details:

Standard of Care treatment for COVID-19 infection was determined by the investigator and included various routes of administration and pharmaceutical forms.

Arm title	Part A: Remdesivir for 10 Days

Arm description:

Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

Arm type	Experimental
Investigational medicinal product name	Remdesivir
Investigational medicinal product code	
Other name	GS-5734™, Veklury®
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered on Day 1 followed by 100 mg on Days 2-10.

Investigational medicinal product name	Standard of care
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Not mentioned

Dosage and administration details:

Standard of Care treatment for COVID-19 infection was determined by the investigator and included various routes of administration and pharmaceutical forms.

Arm title	Part B: Remdesivir for 10 Days (Mechanically Ventilated Group)

Arm description:

Participants on mechanical ventilation received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

Arm type	Experimental
Investigational medicinal product name	Remdesivir
Investigational medicinal product code	
Other name	GS-5734™, Veklury®
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered on Day 1 followed by 100 mg on Days 2-10.

Investigational medicinal product name	Standard of care
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Not mentioned

Dosage and administration details:

Standard of Care treatment for COVID-19 infection was determined by the investigator and included various routes of administration and pharmaceutical forms.

Arm title	Part B: Remdesivir for 10 Days (Extension Group)

Arm description:

Participants who were not mechanically ventilated received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

Arm type	Experimental
Investigational medicinal product name	Remdesivir
Investigational medicinal product code	
Other name	GS-5734™, Veklury®
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered on Day 1 followed by 100 mg on Days 2-10.

Investigational medicinal product name	Standard of care
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Not mentioned

Dosage and administration details:

Standard of Care treatment for COVID-19 infection was determined by the investigator and included various routes of administration and pharmaceutical forms.

Number of subjects in period 1[1]	Part A: Remdesivir (RDV) for 5 Days	Part A: Remdesivir for 10 Days	Part B: Remdesivir for 10 Days (Mechanically Ventilated Group)
Started	200	197	844
Completed	168	164	621
Not completed	32	33	223
Protocol violation	-	-	-
Withdrew Consent	1	-	11
Adverse event, non-fatal	2	1	2
Death	21	28	188
Investigator's Discretion	-	-	-
Non-compliance with study drug	-	-	-
Lost to follow-up	8	4	22

Number of subjects in period 1[1]	Part B: Remdesivir for 10 Days (Extension Group)
Started	3597
Completed	2952
Not completed	645
Protocol violation	1
Withdrew Consent	32
Adverse event, non-fatal	2
Death	371
Investigator's Discretion	3
Non-compliance with study drug	1
Lost to follow-up	235

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 4 participants in Part A and 49 participants in Part B did not receive the treatment and are not included in the subject disposition table.

Baseline characteristics

Reporting groups	
Reporting group title	Part A: Remdesivir (RDV) for 5 Days
Reporting group description:	
Participants received continued standard of care (SOC) therapy together with intravenous (IV) RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-5.	
Reporting group title	Part A: Remdesivir for 10 Days
Reporting group description:	
Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.	
Reporting group title	Part B: Remdesivir for 10 Days (Mechanically Ventilated Group)
Reporting group description:	
Participants on mechanical ventilation received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.	
Reporting group title	Part B: Remdesivir for 10 Days (Extension Group)
Reporting group description:	
Participants who were not mechanically ventilated received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.	

Reporting group values	Part A: Remdesivir (RDV) for 5 Days	Part A: Remdesivir for 10 Days	Part B: Remdesivir for 10 Days (Mechanically Ventilated Group)
Number of subjects	200	197	844
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	60	60	57
standard deviation	± 15.1	± 14.4	± 13.7
Gender categorical			
Units: Subjects			
Female	80	64	312
Male	120	133	532
Race			
Not Permitted means local regulators did not allow collection of ethnicity information.			
Units: Subjects			
American Indian or Alaska Native	2	0	5
Asian	20	25	88
Black	21	23	149
Native Hawaiian or Pacific Islander	1	0	11
White	142	134	376
Not Permitted	0	5	56
Other	14	10	159
Ethnicity			
Not Permitted means local regulators did not allow collection of ethnicity information.			
Units: Subjects			
Hispanic or Latino	47	38	328

Not Hispanic or Latino	152	150	478
Not Permitted	1	9	37
Missing	0	0	1
Clinical Status (7-point ordinal scale)			
The 7-point ordinal scale is an assessment of the clinical status of participant at a given study day:1. Death;2.Hospitalized,on invasive mechanical ventilation or extracorporeal membrane oxygenation(ECMO);3.Hospitalized, on noninvasive ventilation or high-flow oxygen devices;4.Hospitalized,requiring low-flow supplemental oxygen;5.Hospitalized,not requiring supplemental oxygen - requiring ongoing medical care(COVID-19 related or otherwise);6.Hospitalized,not requiring supplemental oxygen - no longer requiring ongoing medical			
Units: Subjects			
Score: 1	0	0	0
Score: 2	4	9	844
Score: 3	49	59	0
Score: 4	113	108	0
Score: 5	34	21	0
Score: 6	0	0	0
Score: 7	0	0	0

Reporting group values	Part B: Remdesivir for 10 Days (Extension Group)	Total	
Number of subjects	3597	4838	
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	58		
standard deviation	± 14.9	-	
Gender categorical			
Units: Subjects			
Female	1351	1807	
Male	2246	3031	
Race			
Not Permitted means local regulators did not allow collection of ethnicity information.			
Units: Subjects			
American Indian or Alaska Native	40	47	
Asian	313	446	
Black	611	804	
Native Hawaiian or Pacific Islander	29	41	
White	1915	2567	
Not Permitted	179	240	
Other	510	693	
Ethnicity			
Not Permitted means local regulators did not allow collection of ethnicity information.			
Units: Subjects			
Hispanic or Latino	1341	1754	
Not Hispanic or Latino	2123	2903	
Not Permitted	129	176	
Missing	4	5	
Clinical Status (7-point ordinal scale)			
The 7-point ordinal scale is an assessment of the clinical status of participant at a given study day:1.			

Death;2.Hospitalized,on invasive mechanical ventilation or extracorporeal membrane oxygenation(ECMO);3.Hospitalized, on noninvasive ventilation or high-flow oxygen devices;4.Hospitalized,requiring low-flow supplemental oxygen;5.Hospitalized,not requiring supplemental oxygen - requiring ongoing medical care(COVID-19 related or otherwise);6.Hospitalized,not requiring supplemental oxygen - no longer requiring ongoing medical			
Units: Subjects			
Score: 1	0	0	
Score: 2	0	857	
Score: 3	1069	1177	
Score: 4	2214	2435	
Score: 5	314	369	
Score: 6	0	0	
Score: 7	0	0	

End points reporting groups

Reporting group title	Part A: Remdesivir (RDV) for 5 Days
Reporting group description:	
Participants received continued standard of care (SOC) therapy together with intravenous (IV) RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-5.	
Reporting group title	Part A: Remdesivir for 10 Days
Reporting group description:	
Participants received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.	
Reporting group title	Part B: Remdesivir for 10 Days (Mechanically Ventilated Group)
Reporting group description:	
Participants on mechanical ventilation received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.	
Reporting group title	Part B: Remdesivir for 10 Days (Extension Group)
Reporting group description:	
Participants who were not mechanically ventilated received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.	

Primary: Part A: Percentage of Participants in Each Clinical Status Category as Assessed by a 7-Point Ordinal Scale on Day 14

End point title	Part A: Percentage of Participants in Each Clinical Status Category as Assessed by a 7-Point Ordinal Scale on Day 14[1]
End point description:	
Clinical status was derived from death,hospital discharge, and the ordinal scale as follows: 1 for all days on or after the death date;7 for all days on or after discharged alive date; last assessment for any missing values. The scale is as follows:1.Death;2. Hospitalized,on invasive mechanical ventilation or ECMO; 3.Hospitalized,on non-invasive ventilation or high flow oxygen devices; 4.Hospitalized, requiring low flow supplemental oxygen; 5.Hospitalized,not requiring supplemental oxygen-requiring ongoing medical care(COVID-19 related or otherwise); 6.Hospitalized,not requiring supplemental oxygen-no longer required ongoing medical care(other than per protocol remdesivir administration);7.Not hospitalized. The odds ratio represents the odds of improvement in the ordinal scale for the Remedesvir for 10 days group vs the Remdesivir for 5 days group. Full Analysis Set included participants who were randomized into part A of the study and received at least 1 dose of study treatment.	
End point type	Primary
End point timeframe:	
Day 14	
Notes:	
[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was not analysed for 'Part B: Remdesivir for 10 Days ' and 'Part B: Remdesivir for 10 Days (Extension Group)'.	

End point values	Part A: Remdesivir (RDV) for 5 Days	Part A: Remdesivir for 10 Days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	197		
Units: percentage of participants				
number (not applicable)				
Score: 1	8.0	10.7		
Score: 2	8.5	16.8		

Score: 3	4.0	5.1		
Score: 4	9.5	7.6		
Score: 5	6.0	6.1		
Score: 6	4.0	1.5		
Score: 7	60.0	52.3		

Statistical analyses

Statistical analysis title	Remdesivir for 5 Days vs Remdesivir for 10 Days
Comparison groups	Part A: Remdesivir for 10 Days v Part A: Remdesivir (RDV) for 5 Days
Number of subjects included in analysis	397
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1563 [2]
Method	Proportional odds model
Parameter estimate	Odds ratio (OR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.507
upper limit	1.115

Notes:

[2] - P-value was calculated using a proportional odds model with treatment as the independent variable and baseline clinical status as a continuous covariate.

Statistical analysis title	Remdesivir for 5 Days vs Remdesivir for 10 Days
Comparison groups	Part A: Remdesivir (RDV) for 5 Days v Part A: Remdesivir for 10 Days
Number of subjects included in analysis	397
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0368 [3]
Method	Proportional odds model
Parameter estimate	Odds ratio (OR)
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.458
upper limit	0.976

Notes:

[3] - P-value was calculated using a proportional odds model with treatment as the independent variable.

Secondary: Part A: Percentage of Participants who Experienced Treatment-Emergent Adverse Events (TEAEs)

End point title	Part A: Percentage of Participants who Experienced Treatment-Emergent Adverse Events (TEAEs)[4]

End point description:

Treatment-emergent Adverse Events (TEAE) were defined as AEs with onset dates on or after the study treatment start date
and no later than 30 days after the permanent discontinuation of the study treatment and/or the AEs that led to
premature discontinuation of study treatment.
Part A: Safety Analysis Set included participants who were randomized into part A of the study and received at
least 1 dose of study treatment.

End point type	Secondary

End point timeframe:

First dose date up to last dose date (maximum: 10 days) plus 30 days

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was not analyzed for 'Part B: Remdesivir for 10 Days ' and 'Part B: Remdesivir for 10 Days (Extension Group)'.

End point values	Part A: Remdesivir (RDV) for 5 Days	Part A: Remdesivir for 10 Days		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	197		
Units: percentage of participants				
number (not applicable)	71.5	75.1		

Statistical analyses

Statistical analysis title	Part A: RDV for 5 Days, Part A: RDV for 10 Days
Comparison groups	Part A: Remdesivir for 10 Days v Part A: Remdesivir (RDV) for 5 Days
Number of subjects included in analysis	397
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7678 [5]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentages
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	10

Notes:

[5] - P-value for comparison of the percentages between the two groups was calculated using the Cochran-Mantel-Haenszel test stratified on baseline clinical status.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Part A: First dose date up to the last dose date (maximum: 10 days) plus 30 days; Part B: First dose date up to the last dose date (maximum: 11 days) plus 30 days

Adverse event reporting additional description:

Part A: Safety Analysis Set included participants who were randomized into part A of the study and received at least 1 dose of study treatment; Part B: Expanded RDV-Treated Analysis Set included participants who received at least 1 dose of study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Part A: Remdesivir (RDV) for 5 Days

Reporting group description:

Participants who were not mechanically ventilated received continued standard of care (SOC) therapy together with intravenous (IV) RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-5.

Reporting group title	Part A: Remdesivir for 10 Days

Reporting group description:

Participants who were not mechanically ventilated received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

Reporting group title	Part B: Remdesivir for 10 Days

Reporting group description:

Participants on mechanical ventilation received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

Reporting group title	Part B: Remdesivir for 10 Days (Extension Group)

Reporting group description:

Participants who were not mechanically ventilated received continued SOC therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2-10.

Serious adverse events	Part A: Remdesivir (RDV) for 5 Days	Part A: Remdesivir for 10 Days	Part B: Remdesivir for 10 Days
Total subjects affected by serious adverse events			
subjects affected / exposed	43 / 200 (21.50%)	68 / 197 (34.52%)	362 / 844 (42.89%)
number of deaths (all causes)	25	28	213
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone cancer			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Hypotension			
subjects affected / exposed	1 / 200 (0.50%)	3 / 197 (1.52%)	23 / 844 (2.73%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Shock			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	7 / 844 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Deep vein thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	6 / 844 (0.71%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Distributive shock			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Circulatory collapse			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Hypertension			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jugular vein thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dry gangrene			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodynamic instability			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			

subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	2 / 200 (1.00%)	4 / 197 (2.03%)	27 / 844 (3.20%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 27
deaths causally related to treatment / all	0 / 2	0 / 4	0 / 25
Pyrexia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	4 / 844 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Death			
subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Brain death			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia malignant			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Asthenia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ disorder			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oedema			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic mass			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine storm			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Social stay hospitalisation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Priapism			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	6 / 200 (3.00%)	10 / 197 (5.08%)	59 / 844 (6.99%)
occurrences causally related to treatment / all	0 / 6	0 / 10	0 / 59
deaths causally related to treatment / all	0 / 5	0 / 3	0 / 38
Acute respiratory failure			
subjects affected / exposed	10 / 200 (5.00%)	18 / 197 (9.14%)	36 / 844 (4.27%)
occurrences causally related to treatment / all	0 / 10	0 / 20	0 / 36
deaths causally related to treatment / all	0 / 3	0 / 6	0 / 30
Hypoxia			

subjects affected / exposed	2 / 200 (1.00%)	4 / 197 (2.03%)	14 / 844 (1.66%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Respiratory distress			
subjects affected / exposed	3 / 200 (1.50%)	5 / 197 (2.54%)	14 / 844 (1.66%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 6
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 200 (0.50%)	4 / 197 (2.03%)	23 / 844 (2.73%)
occurrences causally related to treatment / all	0 / 1	0 / 4	1 / 23
deaths causally related to treatment / all	0 / 1	0 / 3	1 / 19
Pulmonary embolism			
subjects affected / exposed	1 / 200 (0.50%)	4 / 197 (2.03%)	9 / 844 (1.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumothorax			
subjects affected / exposed	2 / 200 (1.00%)	4 / 197 (2.03%)	6 / 844 (0.71%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 2
Dyspnoea			
subjects affected / exposed	4 / 200 (2.00%)	1 / 197 (0.51%)	3 / 844 (0.36%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	1 / 200 (0.50%)	1 / 197 (0.51%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Pneumomediastinum			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			

subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory acidosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	3 / 844 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercapnia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract haemorrhage			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aspiration			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperoxia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung opacity			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pickwickian syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary thrombosis			
subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory gas exchange disorder			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory tract oedema			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachypnoea			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paranoia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Transaminases increased			
subjects affected / exposed	3 / 200 (1.50%)	2 / 197 (1.02%)	6 / 844 (0.71%)
occurrences causally related to treatment / all	3 / 3	2 / 2	4 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatinine increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	5 / 844 (0.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			

subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen consumption increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation abnormal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Troponin increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial test positive			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure abnormal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma scale abnormal			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Creatinine renal clearance abnormal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis marker increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Barotrauma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endotracheal intubation complication			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 200 (0.00%)	2 / 197 (1.02%)	15 / 844 (1.78%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 11
Atrial fibrillation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	10 / 844 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cardio-respiratory arrest			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Acute myocardial infarction			

subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	4 / 844 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Arrhythmia			
subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	3 / 844 (0.36%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Pulseless electrical activity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiogenic shock			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Supraventricular tachycardia			
subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			

subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Atrioventricular block complete			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure acute			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Right ventricular dysfunction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	4 / 844 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cerebral haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	3 / 844 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemorrhage intracranial			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	4 / 844 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Cerebral infarction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain injury			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	3 / 844 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Ischaemic stroke			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral microhaemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Iiird nerve disorder			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy ~ syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure like phenomena			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic stroke			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	4 / 844 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intestinal ischaemia			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	3 / 844 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haematoma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis necrotising			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis intestinalis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			

subjects affected / exposed	1 / 200 (0.50%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute hepatic failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic hepatitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Subcutaneous emphysema			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug eruption			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 200 (1.00%)	3 / 197 (1.52%)	50 / 844 (5.92%)
occurrences causally related to treatment / all	0 / 2	0 / 3	2 / 50
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 6
Renal failure			
subjects affected / exposed	1 / 200 (0.50%)	1 / 197 (0.51%)	13 / 844 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 5
Renal impairment			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	4 / 844 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Anuria			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular necrosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Rhabdomyolysis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	4 / 844 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Compartment syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest wall haematoma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma muscle			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Septic shock			
subjects affected / exposed	2 / 200 (1.00%)	5 / 197 (2.54%)	27 / 844 (3.20%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 27
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 10
Sepsis			
subjects affected / exposed	2 / 200 (1.00%)	1 / 197 (0.51%)	11 / 844 (1.30%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 5
Corona virus infection			
subjects affected / exposed	8 / 200 (4.00%)	10 / 197 (5.08%)	5 / 844 (0.59%)
occurrences causally related to treatment / all	0 / 8	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 5
Pneumonia viral			
subjects affected / exposed	3 / 200 (1.50%)	2 / 197 (1.02%)	18 / 844 (2.13%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 18
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 12
Pneumonia			
subjects affected / exposed	2 / 200 (1.00%)	0 / 197 (0.00%)	6 / 844 (0.71%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 4
Pneumonia bacterial			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	7 / 844 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bacteraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	7 / 844 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	3 / 844 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Abdominal sepsis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Citrobacter bacteraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gangrene			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Subcutaneous abscess			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection bacterial			
subjects affected / exposed	0 / 200 (0.00%)	1 / 197 (0.51%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis septic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metabolic acidosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	2 / 844 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acidosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Diabetes mellitus			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	1 / 844 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			

subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 200 (0.00%)	0 / 197 (0.00%)	0 / 844 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part B: Remdesivir for 10 Days (Extension Group)		
Total subjects affected by serious adverse events			
subjects affected / exposed	851 / 3597 (23.66%)		
number of deaths (all causes)	422		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone cancer			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Vascular disorders			
Hypotension			
subjects affected / exposed	53 / 3597 (1.47%)		
occurrences causally related to treatment / all	0 / 54		
deaths causally related to treatment / all	0 / 9		
Shock			
subjects affected / exposed	11 / 3597 (0.31%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 3		
Deep vein thrombosis			

subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Shock haemorrhagic				
subjects affected / exposed	4 / 3597 (0.11%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Distributive shock				
subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Hypovolaemic shock				
subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Arterial thrombosis				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Circulatory collapse				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Jugular vein thrombosis				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Peripheral artery thrombosis				

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dry gangrene			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Embolism			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemodynamic instability			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Thrombosis			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	32 / 3597 (0.89%)		
occurrences causally related to treatment / all	0 / 32		
deaths causally related to treatment / all	0 / 30		
Pyrexia			

subjects affected / exposed	5 / 3597 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Brain death			
subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Chest pain			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperthermia malignant			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperthermia			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multi-organ disorder			

subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pelvic mass				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Procedural failure				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Cytokine release syndrome				
subjects affected / exposed	5 / 3597 (0.14%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 1			
Cytokine storm				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Drug hypersensitivity				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypersensitivity				

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Social stay hospitalisation			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Priapism			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	254 / 3597 (7.06%)		
occurrences causally related to treatment / all	0 / 255		
deaths causally related to treatment / all	0 / 123		
Acute respiratory failure			
subjects affected / exposed	121 / 3597 (3.36%)		
occurrences causally related to treatment / all	0 / 121		
deaths causally related to treatment / all	0 / 60		
Hypoxia			
subjects affected / exposed	78 / 3597 (2.17%)		
occurrences causally related to treatment / all	0 / 79		
deaths causally related to treatment / all	0 / 17		
Respiratory distress			
subjects affected / exposed	71 / 3597 (1.97%)		
occurrences causally related to treatment / all	0 / 71		
deaths causally related to treatment / all	0 / 18		
Acute respiratory distress syndrome			

subjects affected / exposed	42 / 3597 (1.17%)		
occurrences causally related to treatment / all	0 / 42		
deaths causally related to treatment / all	0 / 25		
Pulmonary embolism			
subjects affected / exposed	32 / 3597 (0.89%)		
occurrences causally related to treatment / all	0 / 32		
deaths causally related to treatment / all	0 / 3		
Pneumothorax			
subjects affected / exposed	25 / 3597 (0.70%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 4		
Dyspnoea			
subjects affected / exposed	26 / 3597 (0.72%)		
occurrences causally related to treatment / all	0 / 26		
deaths causally related to treatment / all	0 / 1		
Respiratory disorder			
subjects affected / exposed	22 / 3597 (0.61%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 9		
Pneumomediastinum			
subjects affected / exposed	3 / 3597 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Respiratory arrest			
subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Pneumonia aspiration			
subjects affected / exposed	3 / 3597 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Respiratory acidosis			

subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Stridor			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypercapnia			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory tract haemorrhage			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspiration			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchiectasis			

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Emphysema			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemothorax			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperoxia			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Interstitial lung disease			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung opacity			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pickwickian syndrome			

subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pneumothorax spontaneous				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary thrombosis				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory gas exchange disorder				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract oedema				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachypnoea				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thoracic haemorrhage				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Mental status changes				

subjects affected / exposed	10 / 3597 (0.28%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 1			
Delirium				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paranoia				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Product issues				
Device dislocation				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Investigations				
Transaminases increased				
subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Creatinine renal clearance decreased				
subjects affected / exposed	4 / 3597 (0.11%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Oxygen saturation decreased				

subjects affected / exposed	5 / 3597 (0.14%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 2			
Aspartate aminotransferase increased				
subjects affected / exposed	4 / 3597 (0.11%)			
occurrences causally related to treatment / all	2 / 4			
deaths causally related to treatment / all	0 / 0			
Alanine aminotransferase increased				
subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 1			
Liver function test increased				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Glomerular filtration rate decreased				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoglobin decreased				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oxygen consumption increased				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oxygen saturation abnormal				

subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Troponin increased				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bacterial test positive				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood alkaline phosphatase increased				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood bilirubin increased				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood pressure abnormal				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coma scale abnormal				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Creatinine renal clearance abnormal				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical condition abnormal				

subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Myocardial necrosis marker increased				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Platelet count decreased				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urine output decreased				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Barotrauma				
subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Endotracheal intubation complication				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rib fracture				

subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haemorrhage				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Cardiac arrest				
subjects affected / exposed	34 / 3597 (0.95%)			
occurrences causally related to treatment / all	0 / 35			
deaths causally related to treatment / all	0 / 25			
Atrial fibrillation				
subjects affected / exposed	12 / 3597 (0.33%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
subjects affected / exposed	11 / 3597 (0.31%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 11			
Acute myocardial infarction				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Arrhythmia				
subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Pulseless electrical activity				

subjects affected / exposed	5 / 3597 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 2		
Bradycardia			
subjects affected / exposed	3 / 3597 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Cardiogenic shock			
subjects affected / exposed	5 / 3597 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 3		
Myocardial infarction			
subjects affected / exposed	4 / 3597 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Cardiac failure			
subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Supraventricular tachycardia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Ventricular tachycardia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block complete			
subjects affected / exposed	3 / 3597 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy			

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure acute			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocardial ischaemia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Right ventricular dysfunction			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angina pectoris			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block second degree			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			

subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cyanosis				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pericarditis				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Right ventricular failure				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress cardiomyopathy				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular arrhythmia				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Ventricular fibrillation				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Nervous system disorders				
Cerebrovascular accident				
subjects affected / exposed	7 / 3597 (0.19%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 2			
Cerebral haemorrhage				

subjects affected / exposed	4 / 3597 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Haemorrhage intracranial			
subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	3 / 3597 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Brain injury			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Ischaemic stroke			
subjects affected / exposed	4 / 3597 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Seizure			
subjects affected / exposed	3 / 3597 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Encephalopathy			
subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Autonomic nervous system imbalance			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain oedema			

subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebellar infarction			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral microhaemorrhage			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coma			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Dizziness			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Embolic stroke			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial paralysis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iiird nerve disorder			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lethargy			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorder			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Posterior reversible encephalopathy ~ syndrome			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure like phenomena			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombotic stroke			

subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxic encephalopathy				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	9 / 3597 (0.25%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 1			
Disseminated intravascular coagulation				
subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Blood loss anaemia				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bicytopenia				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone marrow failure				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coagulopathy				

subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Leukocytosis				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic infarction				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Thrombocytopenia				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Gastrointestinal haemorrhage				
subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Intestinal ischaemia				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Retroperitoneal haemorrhage				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Dysphagia				

subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haematemesis				
subjects affected / exposed	3 / 3597 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Retroperitoneal haematoma				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal wall haematoma				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticular perforation				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				

subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric perforation			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus paralytic			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intra-abdominal haematoma			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis necrotising			

subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumatosis intestinalis				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Vomiting				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Hepatic failure				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute hepatic failure				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertransaminasaemia			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic hepatitis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Biliary colic			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Subcutaneous emphysema			
subjects affected / exposed	4 / 3597 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Decubitus ulcer			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug eruption			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	69 / 3597 (1.92%)		
occurrences causally related to treatment / all	2 / 69		
deaths causally related to treatment / all	0 / 5		
Renal failure			

subjects affected / exposed	17 / 3597 (0.47%)			
occurrences causally related to treatment / all	1 / 17			
deaths causally related to treatment / all	0 / 1			
Renal impairment				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anuria				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Azotaemia				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal tubular necrosis				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Rhabdomyolysis				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Compartment syndrome				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis				

subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chest wall haematoma				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematoma muscle				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Muscle haemorrhage				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Septic shock				
subjects affected / exposed	52 / 3597 (1.45%)			
occurrences causally related to treatment / all	0 / 52			
deaths causally related to treatment / all	0 / 24			
Sepsis				
subjects affected / exposed	34 / 3597 (0.95%)			
occurrences causally related to treatment / all	0 / 34			
deaths causally related to treatment / all	0 / 14			
Corona virus infection				

subjects affected / exposed	22 / 3597 (0.61%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 11		
Pneumonia viral			
subjects affected / exposed	22 / 3597 (0.61%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 13		
Pneumonia			
subjects affected / exposed	24 / 3597 (0.67%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 14		
Pneumonia bacterial			
subjects affected / exposed	4 / 3597 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Bacteraemia			
subjects affected / exposed	3 / 3597 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pneumonia pseudomonal			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal sepsis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary sepsis			

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Superinfection			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Abdominal abscess			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Citrobacter bacteraemia			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocarditis			

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Enterococcal bacteraemia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia bacteraemia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Fungaemia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fungal infection			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gangrene			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia haemophilus			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia staphylococcal			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pseudomonal bacteraemia			

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal sepsis			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Superinfection bacterial			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis septic			
subjects affected / exposed	0 / 3597 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection bacterial			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral myocarditis			

subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral sepsis				
subjects affected / exposed	0 / 3597 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hyperkalaemia				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Metabolic acidosis				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acidosis				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Diabetes mellitus				
subjects affected / exposed	2 / 3597 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Fluid overload				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypernatraemia				
subjects affected / exposed	1 / 3597 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				

subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	2 / 3597 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Decreased appetite			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypovolaemia			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malnutrition			
subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Type 2 diabetes mellitus			

subjects affected / exposed	1 / 3597 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part A: Remdesivir (RDV) for 5 Days	Part A: Remdesivir for 10 Days	Part B: Remdesivir for 10 Days
Total subjects affected by non-serious adverse events			
subjects affected / exposed	79 / 200 (39.50%)	92 / 197 (46.70%)	508 / 844 (60.19%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	10 / 200 (5.00%)	15 / 197 (7.61%)	53 / 844 (6.28%)
occurrences (all)	10	15	59
Aspartate aminotransferase increased			
subjects affected / exposed	8 / 200 (4.00%)	13 / 197 (6.60%)	66 / 844 (7.82%)
occurrences (all)	8	13	75
Transaminases increased			
subjects affected / exposed	3 / 200 (1.50%)	4 / 197 (2.03%)	43 / 844 (5.09%)
occurrences (all)	3	4	43
Vascular disorders			
Hypotension			
subjects affected / exposed	8 / 200 (4.00%)	9 / 197 (4.57%)	99 / 844 (11.73%)
occurrences (all)	9	9	104
Hypertension			
subjects affected / exposed	5 / 200 (2.50%)	6 / 197 (3.05%)	92 / 844 (10.90%)
occurrences (all)	5	6	101
Deep vein thrombosis			
subjects affected / exposed	4 / 200 (2.00%)	5 / 197 (2.54%)	50 / 844 (5.92%)
occurrences (all)	4	5	50
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 200 (3.50%)	7 / 197 (3.55%)	88 / 844 (10.43%)
occurrences (all)	7	7	94
Leukocytosis			

subjects affected / exposed	1 / 200 (0.50%)	1 / 197 (0.51%)	47 / 844 (5.57%)
occurrences (all)	1	1	48
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	9 / 200 (4.50%)	3 / 197 (1.52%)	65 / 844 (7.70%)
occurrences (all)	11	3	86
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	13 / 200 (6.50%)	13 / 197 (6.60%)	78 / 844 (9.24%)
occurrences (all)	13	13	78
Nausea			
subjects affected / exposed	20 / 200 (10.00%)	17 / 197 (8.63%)	28 / 844 (3.32%)
occurrences (all)	20	17	28
Diarrhoea			
subjects affected / exposed	10 / 200 (5.00%)	9 / 197 (4.57%)	54 / 844 (6.40%)
occurrences (all)	10	9	54
Psychiatric disorders			
Insomnia			
subjects affected / exposed	10 / 200 (5.00%)	11 / 197 (5.58%)	17 / 844 (2.01%)
occurrences (all)	10	11	17
Agitation			
subjects affected / exposed	2 / 200 (1.00%)	4 / 197 (2.03%)	74 / 844 (8.77%)
occurrences (all)	2	4	75
Delirium			
subjects affected / exposed	2 / 200 (1.00%)	2 / 197 (1.02%)	60 / 844 (7.11%)
occurrences (all)	2	2	61
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 200 (1.00%)	13 / 197 (6.60%)	113 / 844 (13.39%)
occurrences (all)	2	13	118
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 200 (0.50%)	3 / 197 (1.52%)	48 / 844 (5.69%)
occurrences (all)	1	3	48
Metabolism and nutrition disorders			

Hypokalaemia			
subjects affected / exposed	10 / 200 (5.00%)	12 / 197 (6.09%)	78 / 844 (9.24%)
occurrences (all)	10	12	90
Hyperglycaemia			
subjects affected / exposed	8 / 200 (4.00%)	7 / 197 (3.55%)	62 / 844 (7.35%)
occurrences (all)	8	7	64
Hypernatraemia			
subjects affected / exposed	1 / 200 (0.50%)	2 / 197 (1.02%)	92 / 844 (10.90%)
occurrences (all)	1	2	98

Non-serious adverse events	Part B: Remdesivir for 10 Days (Extension Group)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1258 / 3597 (34.97%)		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	164 / 3597 (4.56%)		
occurrences (all)	168		
Aspartate aminotransferase increased			
subjects affected / exposed	126 / 3597 (3.50%)		
occurrences (all)	134		
Transaminases increased			
subjects affected / exposed	93 / 3597 (2.59%)		
occurrences (all)	94		
Vascular disorders			
Hypotension			
subjects affected / exposed	166 / 3597 (4.61%)		
occurrences (all)	171		
Hypertension			
subjects affected / exposed	67 / 3597 (1.86%)		
occurrences (all)	68		
Deep vein thrombosis			
subjects affected / exposed	55 / 3597 (1.53%)		
occurrences (all)	55		
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	104 / 3597 (2.89%)		
occurrences (all)	114		
Leukocytosis			
subjects affected / exposed	42 / 3597 (1.17%)		
occurrences (all)	42		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	101 / 3597 (2.81%)		
occurrences (all)	115		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	237 / 3597 (6.59%)		
occurrences (all)	239		
Nausea			
subjects affected / exposed	220 / 3597 (6.12%)		
occurrences (all)	226		
Diarrhoea			
subjects affected / exposed	128 / 3597 (3.56%)		
occurrences (all)	132		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	116 / 3597 (3.22%)		
occurrences (all)	117		
Agitation			
subjects affected / exposed	47 / 3597 (1.31%)		
occurrences (all)	47		
Delirium			
subjects affected / exposed	40 / 3597 (1.11%)		
occurrences (all)	40		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	117 / 3597 (3.25%)		
occurrences (all)	118		
Infections and infestations			

Pneumonia subjects affected / exposed occurrences (all)	48 / 3597 (1.33%) 48		
Metabolism and nutrition disorders Hypokalaemia subjects affected / exposed occurrences (all) Hyperglycaemia subjects affected / exposed occurrences (all) Hypernatraemia subjects affected / exposed occurrences (all)	 190 / 3597 (5.28%) 198 92 / 3597 (2.56%) 100 59 / 3597 (1.64%) 60		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 March 2020	Amendment 1: • Revised primary endpoint to allow for more robust analysis • Expanded number of sites and participants globally to meet urgent needs • Divided enrollment into 2 parts: A and B • Included a Mechanically Ventilated Treatment Group and an Extension Treatment Group during enrollment to extend RDV therapy (Part B) • Provided further clarification to the inclusion and exclusion criteria • Included parameters for adolescent participants and adolescent dosing • Revised statistical methodology and analysis due to changes in endpoints and study design • Clarified requirements for oxygen supplementation
20 March 2020	Amendment 2: • Revised informed consent language to include informed consent with a legal representative and those enrolled under ICH E6(R2) 4.8.15 emergency use provisions
12 April 2020	Amendment 3: • Increased number of centers globally • Increased number of participants for enrollment • Removed enrollment limit for the mechanically ventilated treatment group • Revised section on pediatric dosing with minor edits • Added language around discontinuation of study medication • Clarified section on concomitant medications disallowed during study • Added further guidance on pharmacokinetic (PK) assessments and sample collection timepoints • Clarified assessment guidance for laboratory abnormalities • Incorporated changes per the latest administrative amendment (v3)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32459919