



Clinical trial results: Medically Ill Patient Assessment of Rivaroxaban Versus Placebo in Reducing Post-Discharge Venous Thrombo-Embolism Risk Summary

EudraCT number	2014-000305-13
Trial protocol	DK HU CZ IT ES NL LT BG GR LV AT DE GB PT SK HR
Global end of trial date	03 May 2018

Results information

Result version number	v1 (current)
This version publication date	05 May 2019
First version publication date	05 May 2019

Trial information

Trial identification

Sponsor protocol code	RIVAROXDVT3002
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02111564
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development LLC
Sponsor organisation address	920 US Highway 202, Raritan, United States, NJ 08869
Public contact	Clinical Registry group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 May 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	03 May 2018
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 assess the efficacy and safety of rivaroxaban, compared with placebo in the prevention of symptomatic venous thromboembolism events (lower extremity deep vein thrombosis [DVT] and non-fatal pulmonary embolism [PE]) and venous thromboembolism events-related death (death due to PE or death in which PE could not be ruled out as the cause) post hospital discharge in high-risk, medically ill subjects.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices (GCP) and applicable regulatory requirements. Safety assessments included adverse event and International Society on Thrombosis and Haemostasis (ISTH) major bleeding, non-major clinically relevant bleeding, other bleeding and clinical laboratory tests.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 June 2014
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	Argentina: 242
Country: Number of subjects enrolled	Australia: 88
Country: Number of subjects enrolled	Austria: 14
Country: Number of subjects enrolled	Bulgaria: 1428
Country: Number of subjects enrolled	Bosnia and Herzegovina: 597
Country: Number of subjects enrolled	Belarus: 133
Country: Number of subjects enrolled	Brazil: 92
Country: Number of subjects enrolled	Canada: 43
Country: Number of subjects enrolled	Colombia: 140
Country: Number of subjects enrolled	Czech Republic: 231
Country: Number of subjects enrolled	Germany: 17
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	Spain: 383
Country: Number of subjects enrolled	Estonia: 11
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	Georgia: 1762
Country: Number of subjects enrolled	Greece: 131

Country: Number of subjects enrolled	Croatia: 270
Country: Number of subjects enrolled	Hungary: 549
Country: Number of subjects enrolled	Israel: 111
Country: Number of subjects enrolled	Italy: 147
Country: Number of subjects enrolled	Lithuania: 164
Country: Number of subjects enrolled	Latvia: 308
Country: Number of subjects enrolled	Mexico: 32
Country: Number of subjects enrolled	Macedonia, the former Yugoslav Republic of: 902
Country: Number of subjects enrolled	Netherlands: 17
Country: Number of subjects enrolled	Peru: 65
Country: Number of subjects enrolled	Poland: 619
Country: Number of subjects enrolled	Puerto Rico: 1
Country: Number of subjects enrolled	Portugal: 13
Country: Number of subjects enrolled	Romania: 324
Country: Number of subjects enrolled	Russian Federation: 1142
Country: Number of subjects enrolled	Serbia: 609
Country: Number of subjects enrolled	Turkey: 70
Country: Number of subjects enrolled	Ukraine: 854
Country: Number of subjects enrolled	United States: 290
Country: Number of subjects enrolled	South Africa: 205
Worldwide total number of subjects	12019
EEA total number of subjects	4641

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	3655
From 65 to 84 years	7626
85 years and over	738

Subject disposition

Recruitment

Recruitment details:

This study was conducted from 10-June-2014 to 03-May-2018.

Pre-assignment

Screening details:

13708 subjects were screened for eligibility. Of these 12024 subjects were randomized (Rivaroxaban- 6007 and Placebo- 6017). 5 subjects in placebo were excluded from ITT population (2-invalid consent, 3 randomized prior to Health Authority approval).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Rivaroxaban 10 mg or 7.5 mg

Arm description:

Subjects with a creatinine clearance (CrCl) at screening greater than or equal to ($\geq$) 50 milliliter per minute (mL/min) at screening received 10 milligram (mg) rivaroxaban tablet once daily orally and subjects with a creatinine clearance at screening from ≥ 30 to less than ($<$) 50 mL/min at screening received 7.5 mg rivaroxaban tablet once daily for 45 days.

Arm type	Experimental
Investigational medicinal product name	Rivaroxaban
Investigational medicinal product code	
Other name	JNJ-39039039, BAY 59-7939
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects were randomised to receive 10 mg or 7.5 mg rivaroxaban tablet once daily for 45 days.

Arm title	Placebo
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Arm description:

Subjects received matching placebo tablet once daily for 45 days.

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

Dosage and administration details:

Subjects received matching placebo tablet once daily for 45 days.

Number of subjects in period 1	Rivaroxaban 10 mg or 7.5 mg	Placebo
Started	6007	6012
Safety	5982	5980
Completed	5876	5869
Not completed	131	143
Adverse event, serious fatal	92	99
Consent withdrawn by subject	20	20
Adverse event, non serious	11	13
Adverse event, serious non-fatal	6	8
Lost to follow-up	2	3

Baseline characteristics

Reporting groups

Reporting group title	Rivaroxaban 10 mg or 7.5 mg
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Reporting group description:

Subjects with a creatinine clearance (CrCl) at screening greater than or equal to ($\geq$) 50 milliliter per minute (mL/min) at screening received 10 milligram (mg) rivaroxaban tablet once daily orally and subjects with a creatinine clearance at screening from ≥ 30 to less than ($<$) 50 mL/min at screening received 7.5 mg rivaroxaban tablet once daily for 45 days.

Reporting group title	Placebo
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Reporting group description:

Subjects received matching placebo tablet once daily for 45 days.

Reporting group values	Rivaroxaban 10 mg or 7.5 mg	Placebo	Total
Number of subjects	6007	6012	12019
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1809	1846	3655
From 65 to 84 years	3866	3760	7626
85 years and over	332	406	738
Title for AgeContinuous Units: years			
arithmetic mean	69.7	69.7	
standard deviation	± 10.6	± 10.22	-
Title for Gender Units: subjects			
Male	3130	3154	6284
Female	2877	2858	5735

End points

End points reporting groups

Reporting group title	Rivaroxaban 10 mg or 7.5 mg
Reporting group description: Subjects with a creatinine clearance (CrCl) at screening greater than or equal to ($\geq$) 50 milliliter per minute (mL/min) at screening received 10 milligram (mg) rivaroxaban tablet once daily orally and subjects with a creatinine clearance at screening from ≥ 30 to less than ($<$) 50 mL/min at screening received 7.5 mg rivaroxaban tablet once daily for 45 days.	
Reporting group title	Placebo
Reporting group description: Subjects received matching placebo tablet once daily for 45 days.	

Primary: Event Rate Based on the Time to the First Occurrence of Composite of all Symptomatic Venous Thromboembolism (VTE) and VTE-Related Death Adjudicated by Clinical Event Committee (CEC)

End point title	Event Rate Based on the Time to the First Occurrence of Composite of all Symptomatic Venous Thromboembolism (VTE) and VTE-Related Death Adjudicated by Clinical Event Committee (CEC)
End point description: Symptomatic VTE included lower extremity deep vein thrombosis (DVT) and non-fatal pulmonary embolism (PE). Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. Intention-to-treat (ITT) analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.	
End point type	Primary
End point timeframe: Up to Day 45	

End point values	Rivaroxaban 10 mg or 7.5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6007	6012		
Units: Events per 100 patients in 45 days				
number (not applicable)	0.84	1.11		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Rivaroxaban 10 mg or 7.5 mg v Placebo

Number of subjects included in analysis	12019
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.136
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.09

Primary: Event Rate based on Time from Randomization to the First occurrence of Major Bleeding Adjudicated by CEC

End point title	Event Rate based on Time from Randomization to the First occurrence of Major Bleeding Adjudicated by CEC
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End point description:

A major bleeding event was defined using validated International Society on Thrombosis and Haemostasis (ISTH) bleeding criteria. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or last dose + 2 days. The Safety analysis set included all enrolled subjects in the ITT analysis set who received at least 1 dose of study drug.

End point type	Primary
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End point timeframe:

Up to 45 Days

End point values	Rivaroxaban 10 mg or 7.5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5982	5980		
Units: Events per 100 patients in 45 days				
number (not applicable)	0.28	0.15		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Rivaroxaban 10 mg or 7.5 mg v Placebo
Number of subjects included in analysis	11962
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.124
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	1.88

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	4.23

Secondary: Event Rate Based on Time from Randomization to an Occurrence of VTE-Related Death Adjudicated by CEC

End point title	Event Rate Based on Time from Randomization to an Occurrence of VTE-Related Death Adjudicated by CEC
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End point description:

Time from randomization to an occurrence of VTE-related death was assessed. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

End point type	Secondary
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End point timeframe:

Up to Day 45

End point values	Rivaroxaban 10 mg or 7.5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6007	6012		
Units: Events per 100 patients in 45 days				
number (not applicable)	0.72	0.77		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Rivaroxaban 10 mg or 7.5 mg v Placebo
Number of subjects included in analysis	12019
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.751
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.42

Secondary: Event Rate Based on Time from Randomization to the First Occurrence of a Symptomatic Venous Thromboembolism Event (VTE) Adjudicated by CEC

End point title	Event Rate Based on Time from Randomization to the First Occurrence of a Symptomatic Venous Thromboembolism Event (VTE) Adjudicated by CEC
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End point description:

Time from randomization to the first occurrence of a symptomatic VTE was assessed. Symptomatic VTE included lower extremity DVT and non-fatal PE. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

End point type	Secondary
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End point timeframe:

Up to Day 45

End point values	Rivaroxaban 10 mg or 7.5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6007	6012		
Units: Events per 100 patients in 45 days				
number (not applicable)	0.19	0.42		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Rivaroxaban 10 mg or 7.5 mg v Placebo
Number of subjects included in analysis	12019
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.023
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	0.89

Secondary: Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE and All-Cause Mortality (ACM) Adjudicated by CEC

End point title	Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE and All-Cause Mortality (ACM) Adjudicated by CEC
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End point description:

Time from randomization to the first occurrence of a composite of symptomatic VTE and ACM was assessed. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

End point type	Secondary
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End point timeframe:

Up to Day 45

End point values	Rivaroxaban 10 mg or 7.5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6007	6012		
Units: Events per 100 patients in 45 days				
number (not applicable)	1.31	1.80		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Rivaroxaban 10 mg or 7.5 mg v Placebo
Number of subjects included in analysis	12019
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.033
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	0.97

Secondary: Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE, Myocardial Infarction (MI), Non-Hemorrhagic Stroke, and Cardiovascular (CV) Death Adjudicated by CEC

End point title	Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE, Myocardial Infarction (MI), Non-Hemorrhagic Stroke, and Cardiovascular (CV) Death Adjudicated by CEC
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End point description:

Time from randomization to the first occurrence of a composite of symptomatic VTE (lower extremity DVT and non-fatal PE), MI, non-hemorrhagic stroke, and CV death (death due to a known CV cause and death in which a CV cause cannot be ruled out; by this definition, a VTE-related death was considered a CV death) was reported. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or

Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

End point type	Secondary
End point timeframe:	
Up to Day 45	

End point values	Rivaroxaban 10 mg or 7.5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6007	6012		
Units: Events per 100 patients in 45 days				
number (not applicable)	1.58	2.03		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Rivaroxaban 10 mg or 7.5 mg v Placebo
Number of subjects included in analysis	12019
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	1.02

Secondary: Event Rate Based on Time from Randomization to an Occurrence of ACM Adjudicated by CEC

End point title	Event Rate Based on Time from Randomization to an Occurrence of ACM Adjudicated by CEC
End point description:	
Time from randomization to an occurrence of all-cause mortality (ACM) was assessed. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.	
End point type	Secondary
End point timeframe:	
Up to Day 45	

End point values	Rivaroxaban 10 mg or 7.5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6007	6012		
Units: Events per 100 patients in 45 days				
number (not applicable)	1.19	1.49		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Rivaroxaban 10 mg or 7.5 mg v Placebo
Number of subjects included in analysis	12019
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.156
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	1.09

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Approximately 80 days

Adverse event reporting additional description:

Intention-to-treat (ITT) analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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Reporting groups

Reporting group title	Rivaroxaban 10 mg or 7.5 mg
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Reporting group description:

Subjects with a creatinine clearance (CrCl) at screening greater than or equal to ($\geq$) 50 milliliter per minute (mL/min) at screening received 10 milligram (mg) rivaroxaban tablet once daily orally and subjects with a creatinine clearance at screening from ≥ 30 to less than ($<$) 50 mL/min at screening received 7.5 mg rivaroxaban tablet once daily for 45 days.

Reporting group title	Placebo
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Reporting group description:

Subjects received matching placebo tablet once daily for 45 days.

Serious adverse events	Rivaroxaban 10 mg or 7.5 mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	475 / 6007 (7.91%)	493 / 6012 (8.20%)	
number of deaths (all causes)	115	126	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Leukaemia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma of Colon			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Cancer Recurrent			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder Neoplasm			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Cancer			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Neoplasm			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon Cancer Metastatic			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastric Cancer			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic Cancer Metastatic			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Invasive Ductal Breast Carcinoma			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Cancer Metastatic			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Lung Infiltration Malignant			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Neoplasm			
subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung Neoplasm Malignant			
subjects affected / exposed	0 / 6007 (0.00%)	5 / 6012 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Malignant Neoplasm of Unknown Primary Site			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant Pleural Effusion			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinum Neoplasm			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic Neoplasm			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-Hodgkin's Lymphoma			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Small Cell Lung Cancer			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian Cancer			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma Cell Myeloma			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Cancer			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Neoplasm			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid Cancer			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Neoplasm			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous Cell Carcinoma of Lung			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic Dissection			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Stenosis			
subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial Stenosis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Distributive Shock			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Crisis			

subjects affected / exposed	0 / 6007 (0.00%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	5 / 6007 (0.08%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Artery Occlusion			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Artery Thrombosis			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Ischaemia			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post Thrombotic Syndrome			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest Pain			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	25 / 6007 (0.42%)	30 / 6012 (0.50%)	
occurrences causally related to treatment / all	1 / 25	0 / 30	
deaths causally related to treatment / all	1 / 25	0 / 30	
Fatigue			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Oedema Peripheral			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Swelling			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 6007 (0.00%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden Cardiac Death			

subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Systemic Inflammatory Response Syndrome			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Bereavement			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immobile			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute Pulmonary Oedema			
subjects affected / exposed	4 / 6007 (0.07%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute Respiratory Failure			
subjects affected / exposed	7 / 6007 (0.12%)	9 / 6012 (0.15%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 1	
Asthma			

subjects affected / exposed	8 / 6007 (0.13%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 10	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bronchitis Chronic			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	1 / 6007 (0.02%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	81 / 6007 (1.35%)	77 / 6012 (1.28%)	
occurrences causally related to treatment / all	0 / 88	0 / 87	
deaths causally related to treatment / all	0 / 5	0 / 3	
Chronic Respiratory Failure			
subjects affected / exposed	4 / 6007 (0.07%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 6007 (0.02%)	5 / 6012 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial Lung Disease			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lupus Pleurisy			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pickwickian Syndrome			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pleural Effusion			
subjects affected / exposed	2 / 6007 (0.03%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Aspiration			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	3 / 6007 (0.05%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax Spontaneous			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Arterial Hypertension			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Congestion			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Fibrosis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Mass			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Oedema			
subjects affected / exposed	1 / 6007 (0.02%)	4 / 6012 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary Pneumatocele			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Distress			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Failure			
subjects affected / exposed	9 / 6007 (0.15%)	8 / 6012 (0.13%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 5	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion Disorder			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic Attack			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device Dislocation			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Failure			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device Occlusion			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Aspiration Bronchial			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Body Temperature Increased			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Output Decreased			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial Necrosis Marker			

Increased			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Vertebral Fracture			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral Neck Fracture			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur Fracture			
subjects affected / exposed	0 / 6007 (0.00%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head Injury			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip Fracture			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Humerus Fracture			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Anastomosis Complication			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament Rupture			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Limb Fracture			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Injuries			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nerve Injury			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural Pneumothorax			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib Fracture			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Injury			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon Injury			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to Various Agents			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic Lung Injury			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Twiddler's Syndrome			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute Left Ventricular Failure			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina Pectoris			

subjects affected / exposed	3 / 6007 (0.05%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic Valve Incompetence			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Fibrillation			
subjects affected / exposed	13 / 6007 (0.22%)	10 / 6012 (0.17%)	
occurrences causally related to treatment / all	0 / 13	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Flutter			
subjects affected / exposed	3 / 6007 (0.05%)	6 / 6012 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block Complete			
subjects affected / exposed	4 / 6007 (0.07%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular Block Second Degree			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Arrest			

subjects affected / exposed	5 / 6007 (0.08%)	5 / 6012 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 5	0 / 4	
Cardiac Asthma			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Failure			
subjects affected / exposed	51 / 6007 (0.85%)	62 / 6012 (1.03%)	
occurrences causally related to treatment / all	0 / 53	0 / 69	
deaths causally related to treatment / all	0 / 5	0 / 8	
Cardiac Failure Acute			
subjects affected / exposed	14 / 6007 (0.23%)	14 / 6012 (0.23%)	
occurrences causally related to treatment / all	0 / 14	0 / 15	
deaths causally related to treatment / all	0 / 3	0 / 1	
Cardiac Failure Chronic			
subjects affected / exposed	13 / 6007 (0.22%)	8 / 6012 (0.13%)	
occurrences causally related to treatment / all	0 / 13	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 1	
Cardiac Failure Congestive			
subjects affected / exposed	24 / 6007 (0.40%)	25 / 6012 (0.42%)	
occurrences causally related to treatment / all	0 / 27	0 / 26	
deaths causally related to treatment / all	0 / 5	0 / 5	
Cardiac Valve Disease			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Ventricular Thrombosis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-Respiratory Arrest			

subjects affected / exposed	5 / 6007 (0.08%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 5	0 / 2	
Cardiogenic Shock			
subjects affected / exposed	4 / 6007 (0.07%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 2	
Cardiomyopathy			
subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiomyopathy Acute			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiopulmonary Failure			
subjects affected / exposed	4 / 6007 (0.07%)	4 / 6012 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 4	0 / 4	
Congestive Cardiomyopathy			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor Pulmonale			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Disease			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary Artery Stenosis			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diastolic Dysfunction			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive Heart Disease			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Interventricular Septum Rupture			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Cardiomyopathy			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left Ventricular Failure			
subjects affected / exposed	4 / 6007 (0.07%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
Mitral Valve Incompetence			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial Fibrosis			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial Ischaemia			

subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Myocarditis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nodal Rhythm			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right Ventricular Failure			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus Bradycardia			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus Node Dysfunction			
subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular Tachycardia			
subjects affected / exposed	1 / 6007 (0.02%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Extrasystoles			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular Tachycardia			
subjects affected / exposed	3 / 6007 (0.05%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nervous system disorders			
Aphasia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Carotid Artery Occlusion			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid Artery Stenosis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocervical Syndrome			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Demyelinating Polyneuropathy			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial Paralysis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic Coma			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypoglycaemic Encephalopathy			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic Stroke			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar Radiculopathy			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic Intolerance			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	6 / 6007 (0.10%)	5 / 6012 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular Encephalopathy			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral Artery Stenosis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo CNS Origin			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	3 / 6007 (0.05%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune Haemolytic Anaemia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic Anaemia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Motion Sickness			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo Positional			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

Conjunctival Oedema			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exophthalmos			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal Artery Occlusion			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Incarcerated Hernia			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute Abdomen			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Gastritis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis Ischaemic			

subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	3 / 6007 (0.05%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal Ulcer			
subjects affected / exposed	2 / 6007 (0.03%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	2 / 6007 (0.03%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis Haemorrhagic			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical Fistula			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Polyps			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric Ulcer			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Inguinal Hernia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Ischaemia			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Disorder			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Acute			
subjects affected / exposed	2 / 6007 (0.03%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic Ulcer			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic Ulcer Haemorrhage			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic Ulcer Perforation			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal Polyp			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Obstruction			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile Duct Obstruction			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile Duct Stone			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	2 / 6007 (0.03%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Acute			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis Chronic			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	2 / 6007 (0.03%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic Lesion			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis Allergic			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Foot			
subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Necrosis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin Ulcer			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitic Ulcer			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			

Acute Kidney Injury			
subjects affected / exposed	7 / 6007 (0.12%)	8 / 6012 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Kidney Disease			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketonuria			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephritis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic Syndrome			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal Failure			
subjects affected / exposed	3 / 6007 (0.05%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal Impairment			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Retention			

subjects affected / exposed	3 / 6007 (0.05%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back Pain			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment Syndrome			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal Chest Pain			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid Arthritis			
subjects affected / exposed	1 / 6007 (0.02%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral Lesion			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal Abscess			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess Limb			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal Abscess			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Cellulitis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	5 / 6007 (0.08%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary Aspergillosis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	11 / 6007 (0.18%)	10 / 6012 (0.17%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Colitis			

subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Infection			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic Foot Infection			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endocarditis Bacterial			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endotoxic Shock			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	3 / 6007 (0.05%)	4 / 6012 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fungal Oesophagitis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fungal Skin Infection			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	2 / 6007 (0.03%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Salmonella			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Viral			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma Infection			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Helicobacter Infection			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious Colitis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious Pleural Effusion			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective Exacerbation of Bronchiectasis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective Exacerbation of Chronic Obstructive Airways Disease			
subjects affected / exposed	1 / 6007 (0.02%)	4 / 6012 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective Spondylitis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection Site Abscess			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral Discitis			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection			
subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung Abscess			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung Infection			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed	58 / 6007 (0.97%)	48 / 6012 (0.80%)	
occurrences causally related to treatment / all	0 / 59	0 / 49	
deaths causally related to treatment / all	0 / 7	0 / 5	
Pneumonia Bacterial			
subjects affected / exposed	2 / 6007 (0.03%)	4 / 6012 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia Pseudomonal			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Staphylococcal			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative Wound Infection			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Sepsis			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Tuberculosis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 6007 (0.00%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis Chronic			

subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pyoderma			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection			
subjects affected / exposed	3 / 6007 (0.05%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	4 / 6007 (0.07%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 2	
Septic Shock			
subjects affected / exposed	1 / 6007 (0.02%)	4 / 6012 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 4	
Sinusitis			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Infection			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic Abscess			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal Bacteraemia			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal Sepsis			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic Infection			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tracheobronchitis			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculous Pleurisy			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 6007 (0.03%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	11 / 6007 (0.18%)	11 / 6012 (0.18%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection Bacterial			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			

subjects affected / exposed	0 / 6007 (0.00%)	4 / 6012 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Viral Infection			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection Staphylococcal			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 6007 (0.03%)	3 / 6012 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic Metabolic Decompensation			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to Thrive			

subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid Overload			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	1 / 6007 (0.02%)	2 / 6012 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	2 / 6007 (0.03%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoalbuminaemia			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	3 / 6007 (0.05%)	5 / 6012 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			

subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	1 / 6007 (0.02%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overweight			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 6007 (0.00%)	1 / 6012 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitamin B12 Deficiency			
subjects affected / exposed	1 / 6007 (0.02%)	0 / 6012 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Rivaroxaban 10 mg or 7.5 mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	250 / 6007 (4.16%)	280 / 6012 (4.66%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	75 / 6007 (1.25%)	93 / 6012 (1.55%)	
occurrences (all)	81	101	
Nervous system disorders			
Headache			
subjects affected / exposed	114 / 6007 (1.90%)	147 / 6012 (2.45%)	
occurrences (all)	137	174	
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	69 / 6007 (1.15%)	52 / 6012 (0.86%)	
occurrences (all)	80	53	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 June 2015	The overall reason for amendment INT-5 was to modify study procedures, clarify eligibility criteria (including the risk score criterion), and to add subject training materials.
19 June 2015	The overall reason for amendment INT-6 was to clarify prescribed maximum daily dose of thromboprophylactic agents during index hospitalization and to clarify capping of subgroups with certain baseline characteristics or by geographic region or country during enrollment.
31 March 2017	The overall reason for amendment INT-7 was to increase the maximum number of subjects allowed to be enrolled due to a lower than expected blinded pooled event rate in this event driven study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported