Clinical trial results:
An Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) Monotherapy in Subjects with Advanced or Metastatic Squamous Cell (Sq) Non-Small Cell Lung Cancer (NSCLC) who Have Received at Least One Prior Systemic Regimen for the Treatment of Stage IIIb/IV SqNSCLC

Summary

EudraCT number	2014-001285-10
Trial protocol	HU SE DE FI DK PT ES AT GB IE GR RO
Global end of trial date	27 August 2021

Results information

Result version number	v1
This version publication date	11 September 2022
First version publication date	11 September 2022

Trial information

Trial identification

Sponsor protocol code	CA209-171

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02409368
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussee de la Hulpe 185, Brussels, Belgium, 1170
Public contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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	14 October 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 August 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the incidence of high-grade (CTCAE v4.0 Grades 3-4), treatment-related, select adverse events in subjects with advanced or metastatic SqNSCLC who progressed during or after at least 1 systemic therapy.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 April 2015
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	Austria: 9
Country: Number of subjects enrolled	Denmark: 16
Country: Number of subjects enrolled	Finland: 10
Country: Number of subjects enrolled	Greece: 34
Country: Number of subjects enrolled	Hungary: 51
Country: Number of subjects enrolled	Ireland: 3
Country: Number of subjects enrolled	Poland: 81
Country: Number of subjects enrolled	Portugal: 28
Country: Number of subjects enrolled	Romania: 79
Country: Number of subjects enrolled	Russian Federation: 39
Country: Number of subjects enrolled	Spain: 232
Country: Number of subjects enrolled	Sweden: 18
Country: Number of subjects enrolled	United Kingdom: 212
Worldwide total number of subjects	812
EEA total number of subjects	561

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)	331
From 65 to 84 years	480
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

1 subject was ECOG PS 3 and thus outside the scope of the protocol. There were 2 ECOG classification periods during this study. The first was used in Primary Endpoint analysis. The second was used in Baseline Characteristics, Secondary Endpoint, and AE analysis. 1 subject was lost from initial ECOG Classification but included at Study Completion.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	ECOG (PS0)

Arm description:

ECOG Performance Status 0 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks

Arm title	ECOG (PS1)

Arm description:

ECOG Performance Status 1 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks

Arm title	ECOG (PS 2)

Arm description:

ECOG Performance Status 2 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks

Arm title	ECOG (PS3)

Arm description:
ECOG Performance Status 3 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
Nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks

Number of subjects in period 1	ECOG (PS0)	ECOG (PS1)	ECOG (PS 2)
Started	172	537	102
Completed	0	0	0
Not completed	172	537	102
Adverse event, serious fatal	1	5	-
Participant withdrew consent	2	3	4
Study drug toxicity	17	42	7
Other Reasons	5	26	2
Maximum clinical benefit	6	5	-
Participant no longer meets study criteria	3	8	3
Adverse event unrelated to study drug	17	49	12
Lost to follow-up	1	5	-
Poor/non-compliance	-	3	2
Disease Progression	113	382	70
Participant request to discontinue study treatment	6	6	2
Administrative reason by sponsor	1	3	-

Number of subjects in period 1	ECOG (PS3)
Started	1
Completed	0
Not completed	1
Adverse event, serious fatal	-
Participant withdrew consent	-
Study drug toxicity	-

Other Reasons	-
Maximum clinical benefit	-
Participant no longer meets study criteria	-
Adverse event unrelated to study drug	-
Lost to follow-up	-
Poor/non-compliance	-
Disease Progression	1
Participant request to discontinue study treatment	-
Administrative reason by sponsor	-

Baseline characteristics

Reporting groups	
Reporting group title	ECOG (PS0)
Reporting group description:	
ECOG Performance Status 0 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks	
Reporting group title	ECOG (PS1)
Reporting group description:	
ECOG Performance Status 1 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks	
Reporting group title	ECOG (PS 2)
Reporting group description:	
ECOG Performance Status 2 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks	
Reporting group title	ECOG (PS3)
Reporting group description:	
ECOG Performance Status 3 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks	

Reporting group values	ECOG (PS0)	ECOG (PS1)	ECOG (PS 2)
Number of subjects	172	537	102
Age categorical Units: Subjects			
Adults (18-64 years)	83	217	31
From 65-84 years	89	320	70
85 years and over	0	0	1
Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean	63.6	66.1	67.9
standard deviation	± 8.28	± 8.27	± 7.29
Sex: Female, Male Units: Participants			
Female	37	111	22
Male	135	426	80
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	2	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	3	0
White	165	530	102
More than one race	0	0	0
Unknown or Not Reported	7	2	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	13	37	11
Not Hispanic or Latino	159	500	91
Unknown or Not Reported	0	0	0

Reporting group values	ECOG (PS3)	Total	

Number of subjects	1	812	
Age categorical Units: Subjects			
Adults (18-64 years)	0	331	
From 65-84 years	1	480	
85 years and over	0	1	
Age Continuous			
"999"=N/A			
Units: years			
arithmetic mean	71		
standard deviation	± 999	-	
Sex: Female, Male Units: Participants			
Female	1	171	
Male	0	641	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	2	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	3	
White	1	798	
More than one race	0	0	
Unknown or Not Reported	0	9	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	61	
Not Hispanic or Latino	1	751	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	ECOG (PS0)
Reporting group description:	
ECOG Performance Status 0 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks	
Reporting group title	ECOG (PS1)
Reporting group description:	
ECOG Performance Status 1 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks	
Reporting group title	ECOG (PS 2)
Reporting group description:	
ECOG Performance Status 2 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks	
Reporting group title	ECOG (PS3)
Reporting group description:	
ECOG Performance Status 3 nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks	

Primary: Number of Participants With High Grade (Grade 3, 4 and 5) Treatment Related Select Adverse Events

End point title	Number of Participants With High Grade (Grade 3, 4 and 5) Treatment Related Select Adverse Events[1][2]
End point description:	
The total number of participants with high grade treatment related select adverse events.	
End point type	Primary
End point timeframe:	
From first dose to time of analysis of primary endpoint (approximately up to 34 months)	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Summary statistics were not planned for the ECOG PS 3 arm because it was outside the scope of the protocol
[2] - 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: Summary statistics were not planned for the ECOG PS 3 arm because it was outside the scope of the protocol

End point values	ECOG (PS0)	ECOG (PS1)	ECOG (PS 2)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	537	102	
Units: Participants				
Skin	2	7	0	
Gastrointestinal	1	10	0	
Endocrine	4	3	0	
Hepatic	4	12	2	
Pulmonary	2	6	0	
Renal	0	3	1	
Hypersensitivity/ Infusion reaction	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with High Grade Select Adverse Events

End point title	Number of Participants with High Grade Select Adverse

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation subject administered study drug and that does not necessarily have a causal relationship with this treatment. Select AEs include Pulmonary toxicity, Gastrointestinal toxicity (diarrhea or colitis, Endocrinopathies, Hepatotoxicity (including asymptomatic LFT elevations), Renal toxicity, Skin toxicity, and Neurological toxicity.

End point type	Secondary

End point timeframe:

From first dose up to 100 days post last dose (up to 79 months)

Notes:

[3] - 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: Summary statistics were not planned for the ECOG PS 3 arm because it was outside the scope of the protocol

End point values	ECOG (PS0)	ECOG (PS1)	ECOG (PS 2)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	537	102	
Units: Participants				
Skin	2	7	0	
Gastrointestinal	1	11	0	
Endocrine	5	4	0	
Hepatic	6	19	3	
Pulmonary	3	9	1	
Renal	0	7	1	
Hypersensitivity/ Infusion reaction	0	0	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Median Time to Onset of Any Grade Select Adverse Events

End point title	Median Time to Onset of Any Grade Select Adverse Events[4]

End point description:

Median Time to onset of any grade select adverse events reported up to 100 days after last doseMedian Time to onset of any grade select adverse events reported up to 100 days after last dose. An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation subject administered study drug and that does not necessarily have a causal relationship with this treatment. Select AEs include Pulmonary toxicity, Gastrointestinal toxicity (diarrhea or colitis, Endocrinopathies, Hepatotoxicity (including asymptomatic LFT elevations), Renal toxicity, Skin toxicity, and Neurological toxicity.

End point type	Secondary

End point timeframe:

From first dose up to 100 days post last dose (up to approximately 79 months)

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: Summary statistics were not planned for the ECOG PS 3 arm because it was outside the scope of the protocol

End point values	ECOG (PS0)	ECOG (PS1)	ECOG (PS 2)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	537	102	
Units: Weeks				
median (full range (min-max))				
Endrocrine	12.79 (4.0 to 121.6)	10.14 (1.9 to 165.1)	19.86 (6.1 to 55.4)	
Gastrointestinal	11.71 (0.1 to 88.0)	8.86 (0.1 to 228.1)	6.00 (0.3 to 64.3)	
Hepatic	26.64 (1.4 to 234.1)	11.43 (2.0 to 90.1)	8.14 (2.0 to 88.1)	
Pulmonary	33.43 (7.4 to 169.4)	11.50 (0.6 to 166.0)	3.93 (0.1 to 26.3)	
Renal	28.86 (4.1 to 129.9)	22.71 (0.1 to 246.0)	10.29 (1.4 to 52.9)	
Skin	12.14 (0.1 to 92.1)	7.86 (0.1 to 200.1)	14.71 (2.1 to 81.7)	
Hypersensitivity/Infusion Reaction	1.93 (1.7 to 2.1)	2.21 (0.3 to 20.3)	2.14 (2.1 to 28.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Median Time to Resolution of any Grade Select Adverse Events

End point title	Median Time to Resolution of any Grade Select Adverse

End point description:

Median time to resolution of any grade select adverse events reported up to 100 days after last dose. An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation subject administered study drug and that does not necessarily have a causal relationship with this treatment. Select AEs include Pulmonary toxicity, Gastrointestinal toxicity (diarrhea or colitis, Endocrinopathies, Hepatotoxicity (including asymptomatic LFT elevations), Renal toxicity, Skin toxicity, and Neurological toxicity. "99999"=N/A

End point type	Secondary

End point timeframe:

From first dose to up to 100 days post last dose (up to approximately 79 months)

Notes:

[5] - 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: Summary statistics were not planned for the ECOG PS 3 arm because it was outside the scope of the protocol

End point values	ECOG (PS0)	ECOG (PS1)	ECOG (PS 2)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	537	102	
Units: Weeks				
median (confidence interval 95%)				
Endrocrine	99999 (109.00 to 99999)	169.43 (17.86 to 99999)	99999 (6.14 to 99999)	
Gastrointestinal	2.86 (0.43 to 5.14)	2.00 (1.00 to 3.00)	2.00 (0.43 to 5.71)	
Hepatic	4.57 (2.57 to 6.14)	7.71 (4.86 to 17.14)	3.57 (2.14 to 8.14)	
Pulmonary	3.00 (1.43 to 99999)	4.29 (2.14 to 6.00)	2.29 (1.00 to 99999)	
Renal	10.14 (2.14 to 99999)	6.14 (2.29 to 25.14)	59.14 (0.57 to 59.14)	
Skin	99999 (13.57 to 99999)	15.43 (8.71 to 52.86)	5.71 (2.00 to 99999)	
Hypersensitivity/Infusion Reaction	1.14 (0.14 to 2.14)	0.14 (0.14 to 4.43)	0.14 (0.14 to 0.71)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival[6]

End point description:

Overall Survival (OS) is defined as the time from first dosing date to the date of death. A subject who has not died will be censored at last known date alive. OS will be followed continuously while subjects are on treatment and every 3 months via in-person or phone contact after subjects discontinue the study drug.

End point type	Secondary

End point timeframe:

From the first dosing up to the date of death (up to approximately 76 months)

Notes:

[6] - 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: Summary statistics were not planned for the ECOG PS 3 arm because it was outside the scope of the protocol

End point values	ECOG (PS0)	ECOG (PS1)	ECOG (PS 2)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	537	102	
Units: Months				
median (confidence interval 95%)	12.1 (9.9 to 13.4)	10.3 (9.3 to 11.3)	5.2 (3.0 to 7.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)[7]

End point description:

ORR is defined as the percentage of subjects with a best overall response (BOR) of confirmed CR or PR with respect to all treated participants. ORR as assessed by the investigator will be reported.

End point type	Secondary

End point timeframe:

From first dose up to last dose (up to approximately 76 months)

Notes:

[7] - 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: Summary statistics were not planned for the ECOG PS 3 arm because it was outside the scope of the protocol

End point values	ECOG (PS0)	ECOG (PS1)	ECOG (PS 2)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	150	456	64	
Units: Percentage				
number (confidence interval 95%)	8.0 (4.2 to 13.6)	11.0 (8.2 to 14.2)	1.6 (0.0 to 8.4)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: AEs/SAEs are reported from start of the treatment until the end of treatment + 100 days	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups	
Reporting group title	ECOG Performance Status 0
Reporting group description: Nivolumab 3 mg/kg as a 60-minute IV infusion every 2 weeks	
Reporting group title	ECOG Performance Status 2
Reporting group description: Nivolumab 3 mg/kg as a 60-minute IV infusion every 2 weeks	
Reporting group title	ECOG Performance Status 3
Reporting group description: Nivolumab 3 mg/kg as a 60-minute IV infusion every 2 weeks	
Reporting group title	ECOG Performance Status 1
Reporting group description: Nivolumab 3 mg/kg as a 60- minute IV infusion every 2 weeks	

Serious adverse events	ECOG Performance Status 0	ECOG Performance Status 2	ECOG Performance Status 3
Total subjects affected by serious adverse events			
subjects affected / exposed	115 / 172 (66.86%)	84 / 102 (82.35%)	1 / 1 (100.00%)
number of deaths (all causes)	131	90	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Bladder cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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

Bladder neoplasm			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 cancer metastatic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Cancer pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 172 (1.74%)	1 / 102 (0.98%)	0 / 1 (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
Colon cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Follicular thyroid cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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 neoplasm malignant			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Malignant neoplasm progression			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	59 / 172 (34.30%)	58 / 102 (56.86%)	0 / 1 (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
Metastases to central nervous system			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Metastases to lymph nodes			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Non-small cell lung cancer metastatic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Oncologic complication			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Pancreatic carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Small intestine adenocarcinoma			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Tumour associated fever			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Tumour compression			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Tumour pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	2 / 102 (1.96%)	0 / 1 (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			
Deep vein thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Hypertension			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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 ischaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Superior vena cava occlusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Superior vena cava syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Venous thrombosis limb			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
General disorders and administration site conditions			
Asthenia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Death			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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
Hernia obstructive			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Non-cardiac chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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

Oedema peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Pyrexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Sudden cardiac death			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Sudden death			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Systemic inflammatory response syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Immune system disorders			
Drug hypersensitivity			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
Acute respiratory failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	2 / 102 (1.96%)	0 / 1 (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
Aspiration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Asthma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Atelectasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 172 (1.16%)	0 / 102 (0.00%)	0 / 1 (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
Bronchial obstruction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Bronchopneumopathy			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	5 / 102 (4.90%)	0 / 1 (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
Dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 172 (5.23%)	10 / 102 (9.80%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Haemoptysis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 172 (4.07%)	3 / 102 (2.94%)	0 / 1 (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
Hypoxia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Immune-mediated lung disease			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Interstitial lung disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 consolidation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Oesophagobronchial fistula			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Pleural effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 172 (1.74%)	2 / 102 (1.96%)	1 / 1 (100.00%)
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 aspiration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 172 (2.33%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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 embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 172 (1.74%)	0 / 102 (0.00%)	0 / 1 (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 haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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 failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 172 (1.74%)	1 / 102 (0.98%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Tracheal stenosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Psychiatric disorders			
Agitation			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Confusional state			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Mania			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
Alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Liver function test increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
Accidental overdose			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Concussion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	2 / 102 (1.96%)	0 / 1 (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
Femur fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Foreign body in gastrointestinal tract			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Humerus fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Infusion related reaction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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
Overdose			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	2 / 102 (1.96%)	0 / 1 (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
Radiation oesophagitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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

Skull fractured base			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Spinal compression fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Splenic rupture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Tracheal obstruction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 limb fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Congenital, familial and genetic disorders			
Tracheo-oesophageal fistula			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 disorders			
Atrial fibrillation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 172 (1.16%)	2 / 102 (1.96%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 tamponade			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Cardio-respiratory arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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
Cardiomegaly			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Intracardiac thrombus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Left ventricular failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Mitral valve prolapse			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 172 (1.16%)	1 / 102 (0.98%)	0 / 1 (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

Pericardial effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Sinus tachycardia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Supraventricular extrasystoles			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
Brain oedema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Cerebral haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Cerebral infarction			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Cerebrovascular accident			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Epilepsy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Intracranial pressure increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 172 (1.16%)	0 / 102 (0.00%)	0 / 1 (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
Lacunar infarction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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

Loss of consciousness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Monoparesis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Motor dysfunction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Neuropathy peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 sensory neuropathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Spinal cord compression			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Status epilepticus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Syncope			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	3 / 102 (2.94%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 172 (1.16%)	1 / 102 (0.98%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Gastrointestinal disorders			
Abdominal pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 upper			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Anal fissure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Ascites			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Autoimmune colitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Colitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Colitis microscopic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Constipation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Diarrhoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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
Dysphagia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Gastric ulcer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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

Gastrointestinal disorder alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Gastrooesophageal reflux disease alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Immune-mediated enterocolitis alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Inguinal hernia alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 obstruction alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Large intestinal obstruction alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Nausea alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal rupture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Oesophageal stenosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
Autoimmune hepatitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	2 / 102 (1.96%)	0 / 1 (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
Biliary tract disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Cholangitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Drug-induced liver injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Hepatic failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Immune-mediated hepatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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

Jaundice			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Jaundice cholestatic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Liver injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
Angioedema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Rash macular			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Renal and urinary disorders			
Acute kidney injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Calculus urinary			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Leukocyturia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Nephrolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Renal failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 retention			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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 obstruction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Endocrine disorders			
Adrenal insufficiency			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	2 / 172 (1.16%)	0 / 102 (0.00%)	0 / 1 (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
Hypercalcaemia of malignancy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Hyperthyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Hypophysitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 172 (1.16%)	0 / 102 (0.00%)	0 / 1 (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
Thyroiditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
Arthralgia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Arthritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Back pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Bone pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Muscular weakness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Osteonecrosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Patellofemoral pain syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Pathological fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Spinal pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Anal abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Bacteraemia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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 diarrhoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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 infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Biliary sepsis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Bronchitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 172 (2.33%)	1 / 102 (0.98%)	0 / 1 (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
Bronchitis bacterial			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
COVID-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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

COVID-19 pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Clostridium colitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Cystitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	2 / 102 (1.96%)	0 / 1 (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
H1N1 influenza			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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
Infective exacerbation of chronic obstructive airways disease			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 172 (2.91%)	5 / 102 (4.90%)	0 / 1 (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
Mediastinitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	1 / 102 (0.98%)	0 / 1 (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
Meningitis aseptic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Neutropenic sepsis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Parainfluenzae virus infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	20 / 172 (11.63%)	10 / 102 (9.80%)	1 / 1 (100.00%)
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 bacterial			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 cytomegaloviral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 fungal			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 pneumococcal			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 sepsis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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 tuberculosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 infection			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	11 / 172 (6.40%)	3 / 102 (2.94%)	0 / 1 (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
Sepsis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 172 (1.74%)	0 / 102 (0.00%)	0 / 1 (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
Septic shock			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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 infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Streptococcal infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Tracheobronchitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	1 / 102 (0.98%)	0 / 1 (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
Vulval abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Metabolism and nutrition disorders			
Cachexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Dehydration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 172 (1.16%)	1 / 102 (0.98%)	0 / 1 (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
Diabetes mellitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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 metabolic decompensation			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Hypercalcaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	3 / 102 (2.94%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Hyperkalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 172 (0.58%)	0 / 102 (0.00%)	0 / 1 (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
Hypoalbuminaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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
Hypokalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (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

Hyponatraemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 172 (1.16%)	2 / 102 (1.96%)	0 / 1 (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	ECOG Performance Status 1		
Total subjects affected by serious adverse events			
subjects affected / exposed	375 / 537 (69.83%)		
number of deaths (all causes)	446		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 537 (0.37%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder neoplasm			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain cancer metastatic			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cancer pain			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	2 / 537 (0.37%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Follicular thyroid cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm malignant			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm progression			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	206 / 537 (38.36%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to central nervous system			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 537 (0.56%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to lymph nodes			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-small cell lung cancer metastatic				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oncologic complication				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestine adenocarcinoma				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour associated fever				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour compression				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Tumour pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	5 / 537 (0.93%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Deep vein thrombosis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertension				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Superior vena cava occlusion				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Superior vena cava syndrome				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	4 / 537 (0.74%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis limb				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Asthenia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chest pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Death				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	4 / 537 (0.74%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hernia obstructive				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	4 / 537 (0.74%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	8 / 537 (1.49%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Sudden cardiac death				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden death				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	4 / 537 (0.74%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic inflammatory response syndrome				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Drug hypersensitivity				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acute respiratory failure				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspiration				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				

alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atelectasis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchial obstruction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumopathy				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	7 / 537 (1.30%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	28 / 537 (5.21%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	11 / 537 (2.05%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated lung disease				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Interstitial lung disease				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung consolidation				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagobronchial fistula				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Pleural effusion				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	10 / 537 (1.86%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	15 / 537 (2.79%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	6 / 537 (1.12%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary haemorrhage				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	10 / 537 (1.86%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract haemorrhage				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tracheal stenosis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Agitation				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Confusional state				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mania				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver function test increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Accidental overdose			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foreign body in gastrointestinal tract				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infusion related reaction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Overdose				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radiation oesophagitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull fractured base				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic rupture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tracheal obstruction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper limb fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Tracheo-oesophageal fistula				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Atrial fibrillation				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac tamponade				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiomegaly				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intracardiac thrombus				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Left ventricular failure				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mitral valve prolapse				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericarditis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus tachycardia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular extrasystoles				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Brain oedema				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coma				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intracranial pressure increased				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lacunar infarction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Monoparesis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Motor dysfunction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Neuropathy peripheral				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral sensory neuropathy				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal cord compression				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Status epilepticus				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tremor				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	6 / 537 (1.12%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal fissure				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ascites				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune colitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis microscopic				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	7 / 537 (1.30%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Dysphagia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	4 / 537 (0.74%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorder				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated enterocolitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal rupture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal stenosis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Upper gastrointestinal haemorrhage				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Autoimmune hepatitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary tract disorder				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug-induced liver injury				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic failure				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated hepatitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice cholestatic				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver injury				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Angioedema				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash macular				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	4 / 537 (0.74%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Calculus urinary				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukocyturia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	4 / 537 (0.74%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract obstruction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Adrenal insufficiency				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia of malignancy				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperthyroidism				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypophysitis				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypothyroidism				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroiditis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 537 (0.37%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Patellofemoral pain syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pathological fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Spinal pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial diarrhoea				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary sepsis				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	9 / 537 (1.68%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis bacterial				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19 pneumonia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium colitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cystitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
H1N1 influenza				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of chronic obstructive airways disease				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	21 / 537 (3.91%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mediastinitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis aseptic				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	41 / 537 (7.64%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia cytomegaloviral				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia fungal				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Pneumonia pneumococcal				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	25 / 537 (4.66%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	7 / 537 (1.30%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tracheobronchitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 537 (0.56%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	5 / 537 (0.93%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vulval abscess				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Cachexia				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 537 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Decreased appetite				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 537 (0.37%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic metabolic decompensation				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	12 / 537 (2.23%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 537 (0.19%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Hyperkalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoalbuminaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 537 (0.19%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 537 (0.56%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	ECOG Performance Status 0	ECOG Performance Status 2	ECOG Performance Status 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	149 / 172 (86.63%)	86 / 102 (84.31%)	1 / 1 (100.00%)
Vascular disorders			

Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	12 / 172 (6.98%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 172 (5.81%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Asthenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	30 / 172 (17.44%)	15 / 102 (14.71%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	40 / 172 (23.26%)	25 / 102 (24.51%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	14 / 102 (13.73%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Pyrexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 172 (5.23%)	8 / 102 (7.84%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Peripheral swelling			
alternative dictionary used:			

MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	44 / 172 (25.58%)	19 / 102 (18.63%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	44 / 172 (25.58%)	28 / 102 (27.45%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Haemoptysis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 172 (6.40%)	10 / 102 (9.80%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 172 (5.81%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Productive cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	6 / 102 (5.88%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 172 (5.23%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			

Alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	12 / 172 (6.98%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	15 / 172 (8.72%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 172 (5.23%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	7 / 102 (6.86%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	8 / 102 (7.84%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 172 (5.81%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Seizure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	23 / 172 (13.37%)	21 / 102 (20.59%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Eye disorders			

Lacrimation increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	26 / 172 (15.12%)	16 / 102 (15.69%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Constipation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	18 / 172 (10.47%)	16 / 102 (15.69%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	20 / 172 (11.63%)	16 / 102 (15.69%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 172 (5.23%)	9 / 102 (8.82%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Stomatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	7 / 102 (6.86%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 172 (5.23%)	10 / 102 (9.80%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry skin			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	6 / 102 (5.88%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 172 (5.81%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	13 / 172 (7.56%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	25 / 172 (14.53%)	6 / 102 (5.88%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 172 (6.40%)	7 / 102 (6.86%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	24 / 172 (13.95%)	7 / 102 (6.86%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	7 / 102 (6.86%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	6 / 102 (5.88%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Groin pain			
alternative dictionary used:			

MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 172 (6.40%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	18 / 172 (10.47%)	7 / 102 (6.86%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 172 (6.40%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 172 (5.81%)	6 / 102 (5.88%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 172 (5.81%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Oral candidiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Oral fungal infection			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Tooth infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	0 / 102 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	24 / 172 (13.95%)	24 / 102 (23.53%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	6 / 102 (5.88%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 172 (0.00%)	6 / 102 (5.88%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 172 (6.40%)	0 / 102 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	ECOG Performance Status 1		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	472 / 537 (87.90%)		
Vascular disorders			
Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chest pain			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Asthenia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	131 / 537 (24.39%)		
occurrences (all)	0		
Fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	121 / 537 (22.53%)		
occurrences (all)	0		
Non-cardiac chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	34 / 537 (6.33%)		
occurrences (all)	0		
Oedema peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	30 / 537 (5.59%)		
occurrences (all)	0		
Pyrexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	49 / 537 (9.12%)		
occurrences (all)	0		
Influenza like illness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	134 / 537 (24.95%)		
occurrences (all)	0		
Dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	167 / 537 (31.10%)		
occurrences (all)	0		
Haemoptysis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	47 / 537 (8.75%)		
occurrences (all)	0		
Pneumonitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Productive cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Pleural effusion			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	30 / 537 (5.59%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	28 / 537 (5.21%)		
occurrences (all)	0		
Blood creatinine increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	34 / 537 (6.33%)		
occurrences (all)	0		
Weight decreased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	42 / 537 (7.82%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	28 / 537 (5.21%)		
occurrences (all)	0		
Headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	36 / 537 (6.70%)		
occurrences (all)	0		
Seizure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	97 / 537 (18.06%)		
occurrences (all)	0		
Eye disorders			
Lacrimation increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			

Abdominal pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	28 / 537 (5.21%)		
occurrences (all)	0		
Diarrhoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	100 / 537 (18.62%)		
occurrences (all)	0		
Constipation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	80 / 537 (14.90%)		
occurrences (all)	0		
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	71 / 537 (13.22%)		
occurrences (all)	0		
Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	34 / 537 (6.33%)		
occurrences (all)	0		
Stomatitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Pruritus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	58 / 537 (10.80%)		
occurrences (all)	0		
Dry skin			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Rash			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	39 / 537 (7.26%)		
occurrences (all)	0		
Endocrine disorders			
Hyperthyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	37 / 537 (6.89%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Back pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	46 / 537 (8.57%)		
occurrences (all)	0		
Arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	52 / 537 (9.68%)		
occurrences (all)	0		
Musculoskeletal chest pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Pain in extremity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Groin pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Infections and infestations			

Nasopharyngitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences (all)	0			
Lower respiratory tract infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	51 / 537 (9.50%)			
occurrences (all)	0			
Pneumonia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	37 / 537 (6.89%)			
occurrences (all)	0			
Upper respiratory tract infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	29 / 537 (5.40%)			
occurrences (all)	0			
Catheter site infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences (all)	0			
Oral fungal infection				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 537 (0.00%)			
occurrences (all)	0			
Tooth infection				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	147 / 537 (27.37%)		
occurrences (all)	0		
Hypercalcaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	39 / 537 (7.26%)		
occurrences (all)	0		
Hyperkalaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 537 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	27 / 537 (5.03%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 November 2014	The inclusion criteria have been expanded and the exclusion criteria have been minimized in order to expand the subject population. The background section has also been updated to reflect the most recently available data. Expanded palliative local therapy. Randomization after 1 year to subjects who are still benefitting from treatment and achieved a partial or complete response to offer insight into the optimal treatment duration of nivolumab has been added. After 1 year of therapy, subjects will be randomized to continue nivolumab monotherapy (Cohort A) or discontinue therapy with the option of retreatment disease progression (Cohort B). The requirement to have a separate assessment plan for the subjects in the Performance Status 2 (PS2) subgroup has been eliminated. The EQ-5D has been removed. Lung Cancer Symptom Survey has also been eliminated from the subject follow up and decreased while on treatment. Initial tumor assessments have also been changed to occur at Week 8 instead of Week 6. The statistical section has been reformatted. The phrase "rate and frequency" has been changed to the term "incidence" throughout the protocol. The term "Adverse Events of Special Interest" has been changed to "Select Adverse Events." The Performance Status groups were renamed "Subgroup" (from "Cohort") to avoid confusion with the randomized cohorts. Treatment discontinuation criteria were moved from Section 3.5 to the newly created Section 4.6.5.1 to follow the nivolumab protocol structure. The requirement for electrocardiograms has been removed as these tests are not done within the nivolumab clinical development program any more.
18 June 2015	The sample size was reduced from 1800 to 950 (with 15% screening failure rate, 800 will be treated); second-line lung cancer patients will now be allowed to enroll in the study; and the randomization at one year into Cohort A and Cohort B has been removed.
26 October 2016	Adjustment to PS 0-1 and PS 2 subgroup sample numbers. Changes to informed consent procedure for treatment beyond disease progression. Clarification of SAE reporting to within 100 days of discontinuation of drug. Clarification of LCSS and TFT assessments timepoints. Addition of CBC/ TFTs to off-treatment follow-up scheduled lab test. Addition that dose must be recalculated if weight on the day of dosing differs by > 10% from the weight used to calculate the dose.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported