Clinical trial results:
An open-label extension trial of the long-term safety of oral BIBF 1120 in patients with idiopathic pulmonary fibrosis (IPF)

Summary

EudraCT number	2011-002766-21
Trial protocol	GR PT BE ES DE FI GB CZ IT IE
Global end of trial date	01 February 2021

Results information

Result version number	v1
This version publication date	05 February 2022
First version publication date	05 February 2022

Trial information

Trial identification

Sponsor protocol code	1199.33

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01619085
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, 55216
Public contact	Boehringer Ingelheim Call Center, Boehringer Ingelheim, +1 8002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	Boehringer Ingelheim, Call Center, Boehringer Ingelheim, +1 18002430127, clintriage.rdg@boehringer-ingelheim.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	22 February 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 July 2017
Global end of trial reached?	Yes
Global end of trial date	01 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the trial was to assess the long-term safety of oral nintedanib treatment in patients with IPF who had completed 52 weeks of treatment and the follow-up period of Phase III parent trial 1199.32 or 1199.34.

Protection of trial subjects:

All patients were informed that they were free to withdraw their consent at any time during the trial without penalty and prejudice. The signed informed consent forms and any additional patient information were retained by the investigator as part of the trial records. Each patient received a copy of the signed informed consent form and any additional patient information. Patients were informed that their medical records could be examined by authorised monitors or Clinical Quality Assurance auditors of BI, members of the appropriate IEC/IRB, and regulatory authority inspectors. Patients were also informed that all medical information obtained during the course of the trial was considered confidential and used by BI in accordance with the local data protection law. Confidentiality of patient data was ensured by the use of depersonalised patient identification codes (patient numbers). In compliance with local legislation, trial sites in France did not collect information concerning patient race. The terms and conditions of the insurance cover were made available to the investigator and patients in the investigator site file (ISF).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 July 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 22
Country: Number of subjects enrolled	Belgium: 15
Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Chile: 9
Country: Number of subjects enrolled	China: 69
Country: Number of subjects enrolled	Czechia: 8
Country: Number of subjects enrolled	Finland: 9
Country: Number of subjects enrolled	France: 88
Country: Number of subjects enrolled	Germany: 72
Country: Number of subjects enrolled	Greece: 10
Country: Number of subjects enrolled	India: 14
Country: Number of subjects enrolled	Ireland: 1
Country: Number of subjects enrolled	Israel: 14

Country: Number of subjects enrolled	Italy: 63
Country: Number of subjects enrolled	Japan: 85
Country: Number of subjects enrolled	Korea, Republic of: 38
Country: Number of subjects enrolled	Mexico: 5
Country: Number of subjects enrolled	Netherlands: 15
Country: Number of subjects enrolled	Portugal: 12
Country: Number of subjects enrolled	Russian Federation: 2
Country: Number of subjects enrolled	Spain: 18
Country: Number of subjects enrolled	Turkey: 38
Country: Number of subjects enrolled	United Kingdom: 29
Country: Number of subjects enrolled	United States: 115
Worldwide total number of subjects	757
EEA total number of subjects	311

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)	273
From 65 to 84 years	477
85 years and over	7

Subject disposition

Recruitment

Recruitment details:

This was a prospective, open-label extension trial in which patients with Idiopathic pulmonary fibrosis (IPF), who had completed 52 weeks of treatment and the follow-up period in the randomised, double-blind, placebo-controlled parent trials 1199.32/.34 and who needed access to nintedanib outside of the discontinued parent trials 1199.35/.187.

Pre-assignment

Screening details:

All subjects were screened for eligibility prior to participation in the trial. Subjects attended a specialist site which ensured that they (the subjects) strictly met all inclusion and none of the exclusion criteria. Subjects were not to be allocated to a treatment group if any of the entry criteria were violated.

Period 1

Period 1 title	Period 1 - 1199.32/.34/.35/.187
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Total (1199.32/.34)

Arm description:

This group included patients originated from parent trials 1199.32/.34.

For patients participated in parent trials 1199.32/.34, they were to receive continuous dosing of soft gelatin capsules of nintedanib (orally) 150 milligrams (mg) twice daily (bid) in this study unless they had reduced the dose to 100 mg bid trial drug (nintedanib or placebo) in the parent trial; patients receiving 100 mg bid trial drug at the end of the parent trial could receive either nintedanib 100 mg bid or nintedanib 150 mg bid in this study. The daily nintedanib dose for such patients was decided at baseline visit based on discussion between the patient and the investigator. After unblinding of the parent trials, patients randomized to placebo in parent trials, who reduced the dose to 100 mg bid in the parent trial, could increase the dose to nintedanib 150 mg bid in this study. The dose could also be increased to 150 mg at a later time point if medically justified in this study.

Arm type	Experimental
Investigational medicinal product name	Nintedanib
Investigational medicinal product code	BIBF 1120
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Continuous dosing of 100 milligrams or 150 milligrams of soft gelatin capsules of nintedanib (orally) twice daily. In this study, patients were treated with nintedanib until they met one of the discontinuation criteria. Potential reasons for treatment discontinuation include impaired liver function, recurrence of diarrhoea, and progression of idiopathic pulmonary fibrosis.

Arm title	Total (1199.35/.187)

Arm description:

This group included patients originated from parent trials 1199.35/.187.

For patients participated in parent trials 1199.35/.187 (1199.35: open label; 1199.187: randomized placebo-control): patients were to receive the same daily dosage of soft gelatin capsules of nintedanib (orally) as in the parent trials (100 mg bid or 150 mg bid) in this study.

Arm type	Experimental

Investigational medicinal product name	Nintedanib
Investigational medicinal product code	BIBF 1120
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Continuous dosing of 100 milligrams or 150 milligrams of soft gelatin capsules of nintedanib (orally) twice daily. In this study, patients were treated with nintedanib until they met one of the discontinuation criteria. Potential reasons for treatment discontinuation include impaired liver function, recurrence of diarrhoea, and progression of idiopathic pulmonary fibrosis.

Number of subjects in period 1	Total (1199.32/.34)	Total (1199.35/.187)
Started	735	17
Treated	734	17
Completed	734	17
Not completed	1	0
Not treated	1	-

Period 2

Period 2 title	Period 2 - 1199.32/.34 only
Is this the baseline period?	Yes[1]
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Total (1199.32/.34)

Arm description:

This group included patients originated from parent trials 1199.32/.34.

For patients participated in parent trials 1199.32/.34, they were to receive continuous dosing of soft gelatin capsules of nintedanib (orally) 150 milligrams (mg) twice daily (bid) in this study unless they had reduced the dose to 100 mg bid trial drug (nintedanib or placebo) in the parent trial; patients receiving 100 mg bid trial drug at the end of the parent trial could receive either nintedanib 100 mg bid or nintedanib 150 mg bid in this study. The daily nintedanib dose for such patients was decided at baseline visit based on discussion between the patient and the investigator. After unblinding of the parent trials, patients randomized to placebo in parent trials, who reduced the dose to 100 mg bid in the parent trial, could increase the dose to nintedanib 150 mg bid in this study. The dose could also be increased to 150 mg at a later time point if medically justified in this study.

Arm type	Experimental
Investigational medicinal product name	Nintedanib
Investigational medicinal product code	BIBF 1120
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Continuous dosing of 100 milligrams or 150 milligrams of soft gelatin capsules of nintedanib (orally) twice daily. In this study, patients were treated with nintedanib until they met one of the discontinuation criteria. Potential reasons for treatment discontinuation include impaired liver function, recurrence of

diarrhoea, and progression of idiopathic pulmonary fibrosis.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: The group in Period 2 was planned in the protocol using to report the baseline characteristics.

Number of subjects in period 2[2][3]	Total (1199.32/.34)
Started	734
Completed	210
Not completed	524
Adverse event, serious fatal	145
Consent withdrawn by subject	45
Adverse event, non-fatal	231
Other than specified	96
Lost to follow-up	3
Protocol deviation	4

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Baseline characteristics are based on patients who were randomized after successfully completing the screening period and received at least one of the trial medication.

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Period 2 is created to indicate the group used for reporting baseline characteristics and does not reflect the actual chronological order.

Baseline characteristics

Reporting groups	
Reporting group title	Total (1199.32/.34)

Reporting group description:

This group included patients originated from parent trials 1199.32/.34.

For patients participated in parent trials 1199.32/.34, they were to receive continuous dosing of soft gelatin capsules of nintedanib (orally) 150 milligrams (mg) twice daily (bid) in this study unless they had reduced the dose to 100 mg bid trial drug (nintedanib or placebo) in the parent trial; patients receiving 100 mg bid trial drug at the end of the parent trial could receive either nintedanib 100 mg bid or nintedanib 150 mg bid in this study. The daily nintedanib dose for such patients was decided at baseline visit based on discussion between the patient and the investigator. After unblinding of the parent trials, patients randomized to placebo in parent trials, who reduced the dose to 100 mg bid in the parent trial, could increase the dose to nintedanib 150 mg bid in this study. The dose could also be increased to 150 mg at a later time point if medically justified in this study.

Reporting group values	Total (1199.32/.34)	Total	
Number of subjects	734	734	
Age categorical			
Treated set (TS): The data set consisted of all patients who were dispensed trial medication and were documented to have taken at least one dose, and had participated in 1199.32/.34 parent trials.			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	262	262	
From 65-84 years	465	465	
85 years and over	7	7	
Age Continuous			
Treated set (TS): The data set consisted of all patients who were dispensed trial medication and were documented to have taken at least one dose, and had participated in 1199.32/.34 parent trials.			
Units: years			
arithmetic mean	67.2		
standard deviation	± 7.8	-	
Sex: Female, Male			
Treated set (TS): The data set consisted of all patients who were dispensed trial medication and were documented to have taken at least one dose, and had participated in 1199.32/.34 parent trials.			
Units: Participants			
Female	147	147	
Male	587	587	
Race			
Treated set (TS): The data set consisted of all patients who were dispensed trial medication and were documented to have taken at least one dose, and had participated in 1199.32/.34 parent trials.			
Units: Subjects			
American Indian or Alaska Native	1	1	
Asian	214	214	
Native Hawaiian or Other Pacific Islander	0	0	

Black or African American	2	2	
White	431	431	
More than one race	0	0	
Unknown or Not Reported	86	86	

End points

End points reporting groups

Reporting group title	Total (1199.32/.34)

Reporting group description:

This group included patients originated from parent trials 1199.32/.34.

For patients participated in parent trials 1199.32/.34, they were to receive continuous dosing of soft gelatin capsules of nintedanib (orally) 150 milligrams (mg) twice daily (bid) in this study unless they had reduced the dose to 100 mg bid trial drug (nintedanib or placebo) in the parent trial; patients receiving 100 mg bid trial drug at the end of the parent trial could receive either nintedanib 100 mg bid or nintedanib 150 mg bid in this study. The daily nintedanib dose for such patients was decided at baseline visit based on discussion between the patient and the investigator. After unblinding of the parent trials, patients randomized to placebo in parent trials, who reduced the dose to 100 mg bid in the parent trial, could increase the dose to nintedanib 150 mg bid in this study. The dose could also be increased to 150 mg at a later time point if medically justified in this study.

Reporting group title	Total (1199.35/.187)

Reporting group description:

This group included patients originated from parent trials 1199.35/.187.

For patients participated in parent trials 1199.35/.187 (1199.35: open label; 1199.187: randomized placebo-control): patients were to receive the same daily dosage of soft gelatin capsules of nintedanib (orally) as in the parent trials (100 mg bid or 150 mg bid) in this study.

Reporting group title	Total (1199.32/.34)

Reporting group description:

This group included patients originated from parent trials 1199.32/.34.

For patients participated in parent trials 1199.32/.34, they were to receive continuous dosing of soft gelatin capsules of nintedanib (orally) 150 milligrams (mg) twice daily (bid) in this study unless they had reduced the dose to 100 mg bid trial drug (nintedanib or placebo) in the parent trial; patients receiving 100 mg bid trial drug at the end of the parent trial could receive either nintedanib 100 mg bid or nintedanib 150 mg bid in this study. The daily nintedanib dose for such patients was decided at baseline visit based on discussion between the patient and the investigator. After unblinding of the parent trials, patients randomized to placebo in parent trials, who reduced the dose to 100 mg bid in the parent trial, could increase the dose to nintedanib 150 mg bid in this study. The dose could also be increased to 150 mg at a later time point if medically justified in this study.

Primary: Incidence of Adverse Events (AEs)

End point title	Incidence of Adverse Events (AEs)[1]

End point description:

This is the measure for percentage of patients with adverse events (AEs) observed during the trial. The incidence of adverse events (% of patients) over the course of the trial, including the incidence of serious AEs, AEs leading to discontinuation, and fatal AEs are presented.

Treated set (TS): The data set consisted of all patients who were dispensed trial medication and were documented to have taken at least one dose, and had participated in 1199.32/.34 parent trials.

End point type	Primary

End point timeframe:

From first drug administration until end of treatment period + 28 days, in total up to 56.3 months plus 28 days.

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: This endpoint was evaluated only descriptively. Thus, no statistical hypothesis were tested.

End point values	Total (1199.32/.34)			
Subject group type	Reporting group			
Number of subjects analysed	734			
Units: Percentage of patients (%)				
number (not applicable)				
Any AEs	98.5			
AEs leading to discontinuation of trial drug	42.6			
Serious AEs	68.9			
Fatal AEs	23.8			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From the first drug administration until 28 days after the last drug administration, up to 7.5 years.

Adverse event reporting additional description:

Treated set (TS) [and TS35; TS187]: The data set consisted of all patients who were dispensed trial medication and were documented to have taken at least one dose, and had participated in 1199.32/.34 [in 1199.35 for TS35; in 1199.187 for TS187] parent trials. TS (from .32/.34), TS35 (from .35), and TS187 (from .187) are all used to report the AEs.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Placebo (.32/.34)

Reporting group description:

Patients in this group are those who were randomized to placebo arm in parent trials 1199.32/.34 and were treated
with 100 milligrams or 150 milligrams of nintedanib orally twice daily in this study.

Reporting group title	Placebo (.35/.187)

Reporting group description:

Patients in this group are those who were randomized to placebo arm in parent trial 1199.187 and were treated with
150 milligrams or 100 milligrams of nintedanib twice daily in this study.

Reporting group title	Total (1199.32/.34)

Reporting group description:

This group included patients originated from parent trials 1199.32/.34. For patients participated in parent trials 1199.32/.34 (both were randomized, placebo-controlled): patients were to receive continuous dosing of soft gelatin capsules of nintedanib (orally) 150 milligrams (mg) twice daily (bid) in this study unless they had reduced the dose to 100 mg bid trial drug (nintedanib or placebo) in the parent trial; patients receiving 100 mg bid trial drug at the end of the parent trial could receive either nintedanib 100 mg bid or nintedanib 150 mg bid in this study. After unblinding of the parent trials, patients randomized to placebo in parent trials, who reduced the dose to 100 mg bid in the parent trial, could increase the dose to nintedanib 150 mg bid in this study. The dose could also be increased to 150 mg at a later time point if medically justified in this study.

Reporting group title	Nintedanib 150 bid (.32/.34)

Reporting group description:

Patients in this group are those who were randomized to 150 milligrams nintedanib twice daily (bid) arm in the parent
trials 1199.32/.34 and were treated with 100 milligrams or 150 milligrams of nintedanib orally twice daily in this study.

Reporting group title	Nintedanib 100 bid (.35/.187)

Reporting group description:

Patients in this group are those who were participated in the parent trial 1199.35 and were treated with 100
milligrams of nintedanib twice daily (bid) in this study.

Reporting group title	Total (.32/.34/.35/.187)

Reporting group description:

For those from parent trials 1199.32/.34 (both were randomized, placebo-controlled): patients received continuous dosing of soft gelatin capsules of nintedanib (orally) 150 milligrams (mg) twice daily (bid) in this study unless they had reduced the dose to 100 mg bid trial drug (nintedanib (nint.) or placebo) in the parent trial; patients receiving 100 mg bid trial drug at the end of the parent trial could receive either nint. 100 mg bid or nint. 150 mg bid in this study. After unblinding of the parent trials, patients randomized to placebo, who reduced the dose to 100 mg bid, could increase the dose to nint. 150 mg bid in this study. The dose could also be increased to 150 mg at a later time point if medically justified in this study. For those from parent trials 1199.35/.187 (.35: open label; .187: randomized placebo-control): patients received the same daily dosage of soft gelatin capsules of nint. (orally) as in the

parent trials (100 mg bid or 150 mg bid) in this study.

Reporting group title	Total (.35/.187)

Reporting group description:

This group included patients originated from parent trials 1199.35/.187. For patients participated in parent trials
1199.35/.187, they were to receive the same daily dosage of soft gelatin capsules of nintedanib (orally) as in the
parent trials (100 milligrams (mg) twice daily (bid) or 150 mg bid) in this study.

Reporting group title	Nintedanib 150 bid (.35/.187)

Reporting group description:

Patients in this group are those who were treated with 150 milligrams (mg) of nintedanib twice daily (bid) in this study
and were participated in parent trial 1199.35 plus those who were randomized to 150 mg nintedanib bid arm in the
parent trial 1199.187 and were treated with 150 mg or 100 mg nintedanib bid in this study.

Serious adverse events	Placebo (.32/.34)	Placebo (.35/.187)	Total (1199.32/.34)
Total subjects affected by serious adverse events			
subjects affected / exposed	208 / 304 (68.42%)	0 / 7 (0.00%)	509 / 734 (69.35%)
number of deaths (all causes)	78	0	182
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	8 / 734 (1.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer recurrent			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	7 / 734 (0.95%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Lung cancer metastatic			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Lung neoplasm			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	13 / 734 (1.77%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Malignant melanoma			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Metastases to central nervous system			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastases to eye			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastases to liver			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastatic squamous cell carcinoma			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			

subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Oesophageal carcinoma			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural neoplasm			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Prostate cancer			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	6 / 734 (0.82%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
Small intestine carcinoma			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Squamous cell carcinoma			
subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	8 / 734 (1.09%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour of ampulla of Vater			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cutaneous T-cell lymphoma			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Cyanosis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial thrombosis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			

subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Thrombosis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Surgical and medical procedures			
Knee arthroplasty			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transurethral prostatectomy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	11 / 734 (1.50%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication associated with device			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Condition aggravated			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Death			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Disease progression			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 4
Oedema peripheral			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 5
Vascular stent stenosis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital prolapse			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1

Acute respiratory failure			
subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	15 / 734 (2.04%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 17
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 8
Bronchopleural fistula			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic respiratory failure			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	16 / 304 (5.26%)	0 / 7 (0.00%)	38 / 734 (5.18%)
occurrences causally related to treatment / all	0 / 18	0 / 0	0 / 46
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 8
Dyspnoea exertional			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypercapnia			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	9 / 304 (2.96%)	0 / 7 (0.00%)	13 / 734 (1.77%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 14
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
Idiopathic pulmonary fibrosis			
subjects affected / exposed	64 / 304 (21.05%)	0 / 7 (0.00%)	153 / 734 (20.84%)
occurrences causally related to treatment / all	1 / 70	0 / 0	1 / 170
deaths causally related to treatment / all	1 / 28	0 / 0	1 / 57
Interstitial lung disease			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	10 / 734 (1.36%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Lung disorder			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nasal polyps			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumothorax			
subjects affected / exposed	6 / 304 (1.97%)	0 / 7 (0.00%)	15 / 734 (2.04%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 15
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Pneumothorax spontaneous			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary arterial hypertension			
subjects affected / exposed	5 / 304 (1.64%)	0 / 7 (0.00%)	11 / 734 (1.50%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	11 / 304 (3.62%)	0 / 7 (0.00%)	17 / 734 (2.32%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 17
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 5
Pulmonary fibrosis			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	12 / 734 (1.63%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary granuloma			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	22 / 304 (7.24%)	0 / 7 (0.00%)	48 / 734 (6.54%)
occurrences causally related to treatment / all	0 / 25	0 / 0	0 / 54
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Pulmonary infarction			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pulmonary oedema			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory acidosis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory arrest			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			

subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Respiratory failure			
subjects affected / exposed	9 / 304 (2.96%)	0 / 7 (0.00%)	35 / 734 (4.77%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 44
deaths causally related to treatment / all	0 / 6	0 / 0	0 / 22
Respiratory tract haemorrhage			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Confusional state			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood urea increased			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature increased			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrin D dimer increased			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	2 / 2	0 / 0	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Imaging procedure abnormal			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Carbon monoxide poisoning			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	6 / 734 (0.82%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypobarism			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intentional overdose			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative delirium			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation pneumonitis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Porokeratosis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	6 / 734 (0.82%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
Angina pectoris			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angina unstable			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	6 / 304 (1.97%)	0 / 7 (0.00%)	9 / 734 (1.23%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiac arrest			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiac failure			

subjects affected / exposed	6 / 304 (1.97%)	0 / 7 (0.00%)	12 / 734 (1.63%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 15
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 6
Cardiac failure acute			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	7 / 734 (0.95%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardio-respiratory arrest			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cardiogenic shock			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiomyopathy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conduction disorder			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cor pulmonale			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	8 / 734 (1.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cor pulmonale chronic			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	9 / 734 (1.23%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	6 / 734 (0.82%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocardial ischaemia			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocarditis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			

subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prosthetic cardiac valve thrombosis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain hypoxia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery occlusion			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery stenosis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral atrophy			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coma			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	9 / 734 (1.23%)
occurrences causally related to treatment / all	0 / 3	0 / 0	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	1 / 2	0 / 0	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Febrile neutropenia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness unilateral			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sudden hearing loss			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular disorder			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness transient			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dry age-related macular degeneration			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Panophthalmitis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital fat herniation			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior capsule opacification			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Retinal artery occlusion			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein occlusion			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	5 / 304 (1.64%)	0 / 7 (0.00%)	10 / 734 (1.36%)
occurrences causally related to treatment / all	3 / 5	0 / 0	8 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Enteritis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haematochezia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis necrotising			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Protein-losing gastroenteropathy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Obstructive pancreatitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dyskinesia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	6 / 734 (0.82%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cholelithiasis			

subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	9 / 734 (1.23%)
occurrences causally related to treatment / all	0 / 4	0 / 0	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hepatic function abnormal			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular injury			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-alcoholic steatohepatitis			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive hepatopathy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic mass			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous emphysema			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	7 / 734 (0.95%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Anuria			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Glomerulonephritis chronic			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower urinary tract symptoms			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive nephropathy			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint range of motion decreased			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	12 / 734 (1.63%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex encephalitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected cyst			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	7 / 734 (0.95%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	4 / 304 (1.32%)	0 / 7 (0.00%)	9 / 734 (1.23%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Oral fungal infection			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraspinal abscess			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Pneumonia			
subjects affected / exposed	40 / 304 (13.16%)	0 / 7 (0.00%)	99 / 734 (13.49%)
occurrences causally related to treatment / all	0 / 65	0 / 0	2 / 141
deaths causally related to treatment / all	0 / 10	0 / 0	0 / 24
Pneumonia bacterial			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	5 / 734 (0.68%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia influenzal			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Postoperative abscess			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mycosis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	8 / 304 (2.63%)	0 / 7 (0.00%)	13 / 734 (1.77%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	3 / 304 (0.99%)	0 / 7 (0.00%)	8 / 734 (1.09%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 4
Septic shock			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sinusitis			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord abscess			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinea capitis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Upper respiratory tract infection			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	7 / 734 (0.95%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Urinary tract infection			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Viral infection			

subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	4 / 734 (0.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypoglycaemia			
subjects affected / exposed	2 / 304 (0.66%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	3 / 734 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypophagia			
subjects affected / exposed	0 / 304 (0.00%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	2 / 734 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metabolic acidosis			
subjects affected / exposed	1 / 304 (0.33%)	0 / 7 (0.00%)	1 / 734 (0.14%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Nintedanib 150 bid (.32/.34)	Nintedanib 100 bid (.35/.187)	Total (.32/.34/.35/.187)

Total subjects affected by serious adverse events			
subjects affected / exposed	301 / 430 (70.00%)	0 / 2 (0.00%)	510 / 751 (67.91%)
number of deaths (all causes)	104	0	182
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	6 / 430 (1.40%)	0 / 2 (0.00%)	8 / 751 (1.07%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer recurrent			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	7 / 751 (0.93%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Lung cancer metastatic			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lung neoplasm			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	9 / 430 (2.09%)	0 / 2 (0.00%)	13 / 751 (1.73%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Malignant melanoma			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Metastases to central nervous system			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to eye			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to liver			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Oesophageal carcinoma			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural neoplasm			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Prostate cancer			

subjects affected / exposed	4 / 430 (0.93%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	4 / 430 (0.93%)	0 / 2 (0.00%)	6 / 751 (0.80%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Small intestine carcinoma			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma			
subjects affected / exposed	4 / 430 (0.93%)	0 / 2 (0.00%)	8 / 751 (1.07%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma of lung			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Squamous cell carcinoma of skin			

subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	1 / 4	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour of ampulla of Vater			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cutaneous T-cell lymphoma			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial thrombosis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Thrombosis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Surgical and medical procedures			
Knee arthroplasty			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transurethral prostatectomy			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	8 / 430 (1.86%)	0 / 2 (0.00%)	11 / 751 (1.46%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication associated with device			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Condition aggravated			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Death			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Disease progression			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 4
Oedema peripheral			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	4 / 430 (0.93%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 5
Vascular stent stenosis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			

subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital prolapse			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute respiratory failure			
subjects affected / exposed	11 / 430 (2.56%)	0 / 2 (0.00%)	15 / 751 (2.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 17
deaths causally related to treatment / all	0 / 6	0 / 0	0 / 8
Bronchopleural fistula			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic respiratory failure			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	4 / 430 (0.93%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	22 / 430 (5.12%)	0 / 2 (0.00%)	38 / 751 (5.06%)
occurrences causally related to treatment / all	0 / 28	0 / 0	0 / 46
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 8
Dyspnoea exertional			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hypercapnia			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	4 / 430 (0.93%)	0 / 2 (0.00%)	13 / 751 (1.73%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 14
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Idiopathic pulmonary fibrosis			
subjects affected / exposed	89 / 430 (20.70%)	0 / 2 (0.00%)	153 / 751 (20.37%)
occurrences causally related to treatment / all	0 / 100	0 / 0	1 / 170
deaths causally related to treatment / all	0 / 29	0 / 0	1 / 57
Interstitial lung disease			

subjects affected / exposed	7 / 430 (1.63%)	0 / 2 (0.00%)	10 / 751 (1.33%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Lung disorder			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Nasal polyps			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pneumothorax			
subjects affected / exposed	9 / 430 (2.09%)	0 / 2 (0.00%)	15 / 751 (2.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 15
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
Pneumothorax spontaneous			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pulmonary arterial hypertension			
subjects affected / exposed	6 / 430 (1.40%)	0 / 2 (0.00%)	11 / 751 (1.46%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	6 / 430 (1.40%)	0 / 2 (0.00%)	17 / 751 (2.26%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 5
Pulmonary fibrosis			
subjects affected / exposed	9 / 430 (2.09%)	0 / 2 (0.00%)	12 / 751 (1.60%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pulmonary granuloma			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	26 / 430 (6.05%)	0 / 2 (0.00%)	48 / 751 (6.39%)
occurrences causally related to treatment / all	0 / 29	0 / 0	0 / 54
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Pulmonary infarction			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary oedema			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory acidosis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Respiratory arrest			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory failure			
subjects affected / exposed	26 / 430 (6.05%)	0 / 2 (0.00%)	35 / 751 (4.66%)
occurrences causally related to treatment / all	0 / 34	0 / 0	0 / 44
deaths causally related to treatment / all	0 / 16	0 / 0	0 / 22
Respiratory tract haemorrhage			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Completed suicide			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Confusional state			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood urea increased			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature increased			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrin D dimer increased			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glycosylated haemoglobin increased			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	1 / 3	0 / 0	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Imaging procedure abnormal			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Carbon monoxide poisoning			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	6 / 751 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypobarism			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Intentional overdose			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative delirium			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation pneumonitis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Porokeratosis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	5 / 430 (1.16%)	0 / 2 (0.00%)	6 / 751 (0.80%)
occurrences causally related to treatment / all	1 / 5	0 / 0	1 / 6
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Angina pectoris			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Arteriosclerosis coronary artery			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	9 / 751 (1.20%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac arrest			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	6 / 430 (1.40%)	0 / 2 (0.00%)	12 / 751 (1.60%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 15
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 6
Cardiac failure acute			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	6 / 430 (1.40%)	0 / 2 (0.00%)	7 / 751 (0.93%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardio-respiratory arrest			

subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Cardiogenic shock			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiomyopathy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conduction disorder			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cor pulmonale			
subjects affected / exposed	7 / 430 (1.63%)	0 / 2 (0.00%)	8 / 751 (1.07%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Cor pulmonale chronic			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	7 / 430 (1.63%)	0 / 2 (0.00%)	9 / 751 (1.20%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			

subjects affected / exposed	4 / 430 (0.93%)	0 / 2 (0.00%)	6 / 751 (0.80%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 3	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Myocardial ischaemia			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Myocarditis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prosthetic cardiac valve thrombosis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Balance disorder			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain hypoxia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery occlusion			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery stenosis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral atrophy			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Coma			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	6 / 430 (1.40%)	0 / 2 (0.00%)	9 / 751 (1.20%)
occurrences causally related to treatment / all	1 / 6	0 / 0	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	1 / 3	0 / 0	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Febrile neutropenia			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness unilateral			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden hearing loss			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular disorder			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness transient			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dry age-related macular degeneration			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panophthalmitis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital fat herniation			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior capsule opacification			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Retinal artery occlusion			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein occlusion			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	5 / 430 (1.16%)	0 / 2 (0.00%)	10 / 751 (1.33%)
occurrences causally related to treatment / all	5 / 5	0 / 0	8 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Enteritis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Haematochezia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	1 / 3	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis necrotising			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Protein-losing gastroenteropathy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Obstructive pancreatitis			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dyskinesia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	6 / 751 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cholelithiasis			
subjects affected / exposed	5 / 430 (1.16%)	0 / 2 (0.00%)	10 / 751 (1.33%)
occurrences causally related to treatment / all	1 / 5	0 / 0	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hepatic function abnormal			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular injury			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-alcoholic steatohepatitis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive hepatopathy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic mass			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous emphysema			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 430 (0.93%)	0 / 2 (0.00%)	7 / 751 (0.93%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Anuria			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Glomerulonephritis chronic			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower urinary tract symptoms			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive nephropathy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Exostosis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint range of motion decreased			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Infections and infestations			

Bacteraemia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	10 / 430 (2.33%)	0 / 2 (0.00%)	12 / 751 (1.60%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex encephalitis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected cyst			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	7 / 751 (0.93%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	5 / 430 (1.16%)	0 / 2 (0.00%)	9 / 751 (1.20%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oral fungal infection			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraspinal abscess			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Pneumonia			
subjects affected / exposed	59 / 430 (13.72%)	0 / 2 (0.00%)	99 / 751 (13.18%)
occurrences causally related to treatment / all	2 / 76	0 / 0	2 / 141
deaths causally related to treatment / all	0 / 14	0 / 0	0 / 24
Pneumonia bacterial			

subjects affected / exposed	4 / 430 (0.93%)	0 / 2 (0.00%)	5 / 751 (0.67%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pneumonia influenzal			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Postoperative abscess			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mycosis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	5 / 430 (1.16%)	0 / 2 (0.00%)	13 / 751 (1.73%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 15
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Respiratory tract infection bacterial			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	5 / 430 (1.16%)	0 / 2 (0.00%)	8 / 751 (1.07%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 4
Septic shock			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Sinusitis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord abscess			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinea capitis			

subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Upper respiratory tract infection			
subjects affected / exposed	6 / 430 (1.40%)	0 / 2 (0.00%)	7 / 751 (0.93%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Urinary tract infection			
subjects affected / exposed	2 / 430 (0.47%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Viral infection			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			

subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	4 / 751 (0.53%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hypoglycaemia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	3 / 430 (0.70%)	0 / 2 (0.00%)	3 / 751 (0.40%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hypophagia			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	1 / 430 (0.23%)	0 / 2 (0.00%)	2 / 751 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metabolic acidosis			
subjects affected / exposed	0 / 430 (0.00%)	0 / 2 (0.00%)	1 / 751 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Total (.35/.187)	Nintedanib 150 bid (.35/.187)	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 17 (5.88%)	1 / 8 (12.50%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bladder cancer recurrent			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to eye			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural neoplasm			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour of ampulla of Vater			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cutaneous T-cell lymphoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Cyanosis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Knee arthroplasty			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Condition aggravated			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital prolapse			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

Acute pulmonary oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopleural fistula			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercapnia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumomediastinum			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Productive cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary fibrosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary granuloma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory acidosis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood urea increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Body temperature increased			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrin D dimer increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Imaging procedure abnormal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Carbon monoxide poisoning			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypobarism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative delirium			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation pneumonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fever			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Porokeratosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Acute myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conduction disorder			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale chronic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic cardiac valve thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain hypoxia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery occlusion			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral atrophy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			

Deafness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness transient			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry age-related macular degeneration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Glaucoma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panophthalmitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital fat herniation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior capsule opacification			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic pseudocyst			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Protein-losing gastroenteropathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dyskinesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	1 / 17 (5.88%)	1 / 8 (12.50%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic function abnormal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive hepatopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic mass			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous emphysema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis chronic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower urinary tract symptoms			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive nephropathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prerenal failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Thyroid mass			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondropathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint range of motion decreased			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis bacterial			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis infectious			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes simplex encephalitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected cyst			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral fungal infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraspinal abscess			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mycosis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinovirus infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinea capitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complicated appendicitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophagia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			

subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo (.32/.34)	Placebo (.35/.187)	Total (1199.32/.34)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	281 / 304 (92.43%)	3 / 7 (42.86%)	671 / 734 (91.42%)
Investigations			
Weight decreased			
subjects affected / exposed	63 / 304 (20.72%)	0 / 7 (0.00%)	123 / 734 (16.76%)
occurrences (all)	67	0	132
Vascular disorders			
Hypertension			
subjects affected / exposed	23 / 304 (7.57%)	1 / 7 (14.29%)	49 / 734 (6.68%)
occurrences (all)	26	1	53
Nervous system disorders			
Dizziness			
subjects affected / exposed	23 / 304 (7.57%)	0 / 7 (0.00%)	48 / 734 (6.54%)
occurrences (all)	31	0	64
Headache			
subjects affected / exposed	18 / 304 (5.92%)	0 / 7 (0.00%)	42 / 734 (5.72%)
occurrences (all)	20	0	45
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	18 / 304 (5.92%)	0 / 7 (0.00%)	39 / 734 (5.31%)
occurrences (all)	22	0	45
Chest pain			
subjects affected / exposed	15 / 304 (4.93%)	0 / 7 (0.00%)	39 / 734 (5.31%)
occurrences (all)	17	0	44
Fatigue			

subjects affected / exposed	32 / 304 (10.53%)	0 / 7 (0.00%)	68 / 734 (9.26%)
occurrences (all)	39	0	79
Oedema peripheral			
subjects affected / exposed	17 / 304 (5.59%)	0 / 7 (0.00%)	50 / 734 (6.81%)
occurrences (all)	20	0	64
Pyrexia			
subjects affected / exposed	15 / 304 (4.93%)	0 / 7 (0.00%)	42 / 734 (5.72%)
occurrences (all)	15	0	45
Eye disorders			
Cataract			
subjects affected / exposed	8 / 304 (2.63%)	0 / 7 (0.00%)	26 / 734 (3.54%)
occurrences (all)	10	0	28
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	32 / 304 (10.53%)	0 / 7 (0.00%)	63 / 734 (8.58%)
occurrences (all)	46	0	80
Abdominal pain upper			
subjects affected / exposed	21 / 304 (6.91%)	0 / 7 (0.00%)	48 / 734 (6.54%)
occurrences (all)	24	0	56
Constipation			
subjects affected / exposed	26 / 304 (8.55%)	0 / 7 (0.00%)	57 / 734 (7.77%)
occurrences (all)	30	0	66
Diarrhoea			
subjects affected / exposed	213 / 304 (70.07%)	2 / 7 (28.57%)	514 / 734 (70.03%)
occurrences (all)	504	2	1168
Nausea			
subjects affected / exposed	70 / 304 (23.03%)	0 / 7 (0.00%)	146 / 734 (19.89%)
occurrences (all)	112	0	206
Vomiting			
subjects affected / exposed	36 / 304 (11.84%)	0 / 7 (0.00%)	89 / 734 (12.13%)
occurrences (all)	76	0	155
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	66 / 304 (21.71%)	0 / 7 (0.00%)	166 / 734 (22.62%)
occurrences (all)	95	0	224
Dyspnoea			

subjects affected / exposed	48 / 304 (15.79%)	0 / 7 (0.00%)	118 / 734 (16.08%)
occurrences (all)	54	0	134
Idiopathic pulmonary fibrosis			
subjects affected / exposed	32 / 304 (10.53%)	0 / 7 (0.00%)	80 / 734 (10.90%)
occurrences (all)	34	0	86
Productive cough			
subjects affected / exposed	12 / 304 (3.95%)	0 / 7 (0.00%)	36 / 734 (4.90%)
occurrences (all)	13	0	41
Psychiatric disorders			
Anxiety			
subjects affected / exposed	17 / 304 (5.59%)	0 / 7 (0.00%)	26 / 734 (3.54%)
occurrences (all)	18	0	27
Insomnia			
subjects affected / exposed	14 / 304 (4.61%)	0 / 7 (0.00%)	36 / 734 (4.90%)
occurrences (all)	14	0	36
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	18 / 304 (5.92%)	0 / 7 (0.00%)	49 / 734 (6.68%)
occurrences (all)	20	0	59
Back pain			
subjects affected / exposed	28 / 304 (9.21%)	0 / 7 (0.00%)	57 / 734 (7.77%)
occurrences (all)	33	0	67
Myalgia			
subjects affected / exposed	10 / 304 (3.29%)	0 / 7 (0.00%)	21 / 734 (2.86%)
occurrences (all)	11	0	25
Infections and infestations			
Bronchitis			
subjects affected / exposed	54 / 304 (17.76%)	0 / 7 (0.00%)	145 / 734 (19.75%)
occurrences (all)	99	0	255
Influenza			
subjects affected / exposed	11 / 304 (3.62%)	0 / 7 (0.00%)	35 / 734 (4.77%)
occurrences (all)	11	0	50
Lower respiratory tract infection			
subjects affected / exposed	14 / 304 (4.61%)	0 / 7 (0.00%)	40 / 734 (5.45%)
occurrences (all)	39	0	96
Respiratory tract infection			

subjects affected / exposed	15 / 304 (4.93%)	0 / 7 (0.00%)	47 / 734 (6.40%)
occurrences (all)	23	0	88
Rhinitis			
subjects affected / exposed	18 / 304 (5.92%)	0 / 7 (0.00%)	39 / 734 (5.31%)
occurrences (all)	19	0	44
Upper respiratory tract infection			
subjects affected / exposed	38 / 304 (12.50%)	0 / 7 (0.00%)	109 / 734 (14.85%)
occurrences (all)	54	0	177
Nasopharyngitis			
subjects affected / exposed	62 / 304 (20.39%)	0 / 7 (0.00%)	152 / 734 (20.71%)
occurrences (all)	125	0	264
Pneumonia			
subjects affected / exposed	19 / 304 (6.25%)	0 / 7 (0.00%)	45 / 734 (6.13%)
occurrences (all)	24	0	54
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	58 / 304 (19.08%)	0 / 7 (0.00%)	104 / 734 (14.17%)
occurrences (all)	68	0	120

Non-serious adverse events	Nintedanib 150 bid (.32/.34)	Nintedanib 100 bid (.35/.187)	Total (.32/.34/.35/.187)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	390 / 430 (90.70%)	1 / 2 (50.00%)	677 / 751 (90.15%)
Investigations			
Weight decreased			
subjects affected / exposed	60 / 430 (13.95%)	0 / 2 (0.00%)	123 / 751 (16.38%)
occurrences (all)	65	0	132
Vascular disorders			
Hypertension			
subjects affected / exposed	26 / 430 (6.05%)	0 / 2 (0.00%)	50 / 751 (6.66%)
occurrences (all)	27	0	54
Nervous system disorders			
Dizziness			
subjects affected / exposed	25 / 430 (5.81%)	0 / 2 (0.00%)	48 / 751 (6.39%)
occurrences (all)	33	0	64
Headache			
subjects affected / exposed	24 / 430 (5.58%)	0 / 2 (0.00%)	42 / 751 (5.59%)
occurrences (all)	25	0	45

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	21 / 430 (4.88%)	0 / 2 (0.00%)	39 / 751 (5.19%)
occurrences (all)	23	0	45
Chest pain			
subjects affected / exposed	24 / 430 (5.58%)	0 / 2 (0.00%)	39 / 751 (5.19%)
occurrences (all)	27	0	44
Fatigue			
subjects affected / exposed	36 / 430 (8.37%)	0 / 2 (0.00%)	68 / 751 (9.05%)
occurrences (all)	40	0	79
Oedema peripheral			
subjects affected / exposed	33 / 430 (7.67%)	0 / 2 (0.00%)	50 / 751 (6.66%)
occurrences (all)	44	0	64
Pyrexia			
subjects affected / exposed	27 / 430 (6.28%)	0 / 2 (0.00%)	42 / 751 (5.59%)
occurrences (all)	30	0	45
Eye disorders			
Cataract			
subjects affected / exposed	18 / 430 (4.19%)	0 / 2 (0.00%)	27 / 751 (3.60%)
occurrences (all)	18	0	30
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	31 / 430 (7.21%)	0 / 2 (0.00%)	63 / 751 (8.39%)
occurrences (all)	34	0	80
Abdominal pain upper			
subjects affected / exposed	27 / 430 (6.28%)	0 / 2 (0.00%)	48 / 751 (6.39%)
occurrences (all)	32	0	56
Constipation			
subjects affected / exposed	31 / 430 (7.21%)	0 / 2 (0.00%)	57 / 751 (7.59%)
occurrences (all)	36	0	66
Diarrhoea			
subjects affected / exposed	301 / 430 (70.00%)	0 / 2 (0.00%)	516 / 751 (68.71%)
occurrences (all)	664	0	1170
Nausea			
subjects affected / exposed	76 / 430 (17.67%)	0 / 2 (0.00%)	146 / 751 (19.44%)
occurrences (all)	94	0	206

Vomiting			
subjects affected / exposed	53 / 430 (12.33%)	0 / 2 (0.00%)	89 / 751 (11.85%)
occurrences (all)	79	0	155
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	100 / 430 (23.26%)	0 / 2 (0.00%)	166 / 751 (22.10%)
occurrences (all)	129	0	224
Dyspnoea			
subjects affected / exposed	70 / 430 (16.28%)	0 / 2 (0.00%)	119 / 751 (15.85%)
occurrences (all)	80	0	135
Idiopathic pulmonary fibrosis			
subjects affected / exposed	48 / 430 (11.16%)	0 / 2 (0.00%)	80 / 751 (10.65%)
occurrences (all)	52	0	86
Productive cough			
subjects affected / exposed	24 / 430 (5.58%)	0 / 2 (0.00%)	36 / 751 (4.79%)
occurrences (all)	28	0	41
Psychiatric disorders			
Anxiety			
subjects affected / exposed	9 / 430 (2.09%)	0 / 2 (0.00%)	26 / 751 (3.46%)
occurrences (all)	9	0	27
Insomnia			
subjects affected / exposed	22 / 430 (5.12%)	0 / 2 (0.00%)	36 / 751 (4.79%)
occurrences (all)	22	0	36
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	31 / 430 (7.21%)	0 / 2 (0.00%)	49 / 751 (6.52%)
occurrences (all)	39	0	59
Back pain			
subjects affected / exposed	29 / 430 (6.74%)	0 / 2 (0.00%)	57 / 751 (7.59%)
occurrences (all)	34	0	67
Myalgia			
subjects affected / exposed	11 / 430 (2.56%)	0 / 2 (0.00%)	22 / 751 (2.93%)
occurrences (all)	14	0	26
Infections and infestations			
Bronchitis			

subjects affected / exposed	91 / 430 (21.16%)	0 / 2 (0.00%)	145 / 751 (19.31%)
occurrences (all)	156	0	255
Influenza			
subjects affected / exposed	24 / 430 (5.58%)	1 / 2 (50.00%)	36 / 751 (4.79%)
occurrences (all)	39	1	51
Lower respiratory tract infection			
subjects affected / exposed	26 / 430 (6.05%)	0 / 2 (0.00%)	40 / 751 (5.33%)
occurrences (all)	57	0	96
Respiratory tract infection			
subjects affected / exposed	32 / 430 (7.44%)	0 / 2 (0.00%)	47 / 751 (6.26%)
occurrences (all)	65	0	88
Rhinitis			
subjects affected / exposed	21 / 430 (4.88%)	0 / 2 (0.00%)	39 / 751 (5.19%)
occurrences (all)	25	0	44
Upper respiratory tract infection			
subjects affected / exposed	71 / 430 (16.51%)	0 / 2 (0.00%)	109 / 751 (14.51%)
occurrences (all)	123	0	177
Nasopharyngitis			
subjects affected / exposed	90 / 430 (20.93%)	0 / 2 (0.00%)	152 / 751 (20.24%)
occurrences (all)	139	0	264
Pneumonia			
subjects affected / exposed	26 / 430 (6.05%)	0 / 2 (0.00%)	45 / 751 (5.99%)
occurrences (all)	30	0	54
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	46 / 430 (10.70%)	0 / 2 (0.00%)	104 / 751 (13.85%)
occurrences (all)	52	0	120

Non-serious adverse events	Total (.35/.187)	Nintedanib 150 bid (.35/.187)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 17 (35.29%)	2 / 8 (25.00%)	
Investigations			
Weight decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			

Hypertension			
subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Cataract			
subjects affected / exposed	1 / 17 (5.88%)	1 / 8 (12.50%)	
occurrences (all)	2	2	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			

subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Constipation subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Diarrhoea subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 2	0 / 8 (0.00%) 0	
Nausea subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Vomiting subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Dyspnoea subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	1 / 8 (12.50%) 1	
Idiopathic pulmonary fibrosis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Productive cough subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Insomnia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 8 (12.50%)	
occurrences (all)	1	1	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	1 / 17 (5.88%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			

Decreased appetite subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 8 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 October 2012	• Additional guidance concerning the washout of prior bronchodilator therapy on enrolment into the trial was added. • A recommendation was provided that the trial medication be discontinued if patients showed signs of progression of IPF. • It was specified that blood collection could be conducted outside of the trial site in cases of liver enzyme elevation.
09 January 2015	The medical background information and the benefit risk assessment were updated based on the results of the parent trials 1199.32 and 1199.34 and subsequent changes to the Investigator's Brochure (IB). • The exclusion criterion 11, requiring men to use a contraception method was removed. • It was clarified that the nintedanib dose could be re-escalated to 150 mg bid for patients entering the extension trial for whom the treatment dose had been reduced in the parent trials. In addition, patients who had reduced treatment dose in trial 1199.33 due to AEs were allowed to re-escalate the dose to 150 mg bid at any time, if medically justified. • Additional safety and efficacy endpoints were defined. • The plan to perform interim analyses every 48 weeks after the second interim analysis was cancelled. Additional interim analyses were to be performed if requested by Health Authorities or for publication purposes.
28 March 2017	• Since nintedanib (Ofev®) is commercially available, trial 1199.33 was discontinued in countries where nintedanib is accessible on the market. • The final complete analysis was planned. • Guidance concerning patients who continue treatment after data bank lock (DBL) for the final analysis (i.e. patients in countries without access to nintedanib treatment) was added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported