



Clinical trial results:

A RANDOMIZED PHASE 2 TRIAL OF AXITINIB AND TRC105 VERSUS AXITINIB ALONE (INCLUDING A LEAD-IN PHASE 1B DOSE-ESCALATION PORTION) IN PATIENTS WITH ADVANCED OR METASTATIC RENAL CELL CARCINOMA

Summary

EudraCT number	2015-003436-13
Trial protocol	HU GB PL CZ
Global end of trial date	12 June 2019

Results information

Result version number	v1 (current)
This version publication date	02 June 2021
First version publication date	02 June 2021

Trial information

Trial identification

Sponsor protocol code	105RC101
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01806064
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	TRACON Pharmaceuticals, Inc.
Sponsor organisation address	4350 La Jolla Village Drive, Suite 800, San Diego, United States, 92010
Public contact	Study Manager, TRACON Pharmaceuticals Inc., +1 8585500780, clinicaltrials@traconpharma.com
Scientific contact	Study Manager, TRACON Pharmaceuticals Inc., +1 8585500780, clinicaltrials@traconpharma.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	12 June 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 December 2018
Global end of trial reached?	Yes
Global end of trial date	12 June 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase 1b: To evaluate safety and tolerability and determine a recommended phase 2 dose for TRC105 when added to standard dose axitinib in patients with renal cell carcinoma.

Phase 2: To estimate the PFS of patients with advanced or metastatic RCC by RECIST 1.1 criteria in patients treated with axitinib and TRC105 compared to those treated with axitinib alone, following failure of one prior VEGF inhibitor

Protection of trial subjects:

Safety parameters were reviewed by a chartered Safety Review Team that reviewed data for all TRC105 studies quarterly and a chartered Data Monitoring Committee (DMC) that periodically reviewed accumulating safety and efficacy data from this study. An interim analysis for futility was conducted by the DMC when 55 events occurred. At the interim analysis, the conditional power based on the observed hazard ratio was estimated. If the conditional power was less than 25%, the DMC could recommend the sponsor that the study be terminated for futility. This interim analysis did not consider the possibility of early termination on the basis of superior efficacy.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 December 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	Czechia: 13
Country: Number of subjects enrolled	Hungary: 21
Country: Number of subjects enrolled	United States: 138
Worldwide total number of subjects	173
EEA total number of subjects	34

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	93
From 65 to 84 years	80
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

23 patients enrolled in phase 1b portion. 150 patients randomized in the phase 2 portion.

Pre-assignment

Screening details:

Patients with advanced or metastatic renal cell carcinoma.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	P2 Arm A: 5 mg Axitinib BID
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Arm description:

Phase 2 Arm A: 5 mg Axitinib twice daily

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

Dosage and administration details:

1mg and 5mg tablets

Arm title	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
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Arm description:

Phase 2 Arm B: 10 mg/kg TRC105 weekly + 5 mg Axitinib twice daily

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

Dosage and administration details:

5mg tablets twice daily

Investigational medicinal product name	TRC 105
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

10mg/kg Weekly

Arm title	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID
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Arm description:

Phase 1b Dose Level 1: 8 mg/kg TRC105 weekly in combination with 5 mg Axitinib twice daily

Arm type	Experimental
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Investigational medicinal product name	Axitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
5mg tablets twice daily	
Investigational medicinal product name	TRC 105
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
8mg/kg Weekly	
Arm title	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Arm description:	
Phase 1b Dose Level 2: 10 mg/kg TRC105 weekly in combination with 5 mg Axitinib twice daily	
Arm type	Experimental
Investigational medicinal product name	Axitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
5mg tablets twice daily	
Investigational medicinal product name	TRC 105
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10mg/kg Weekly	
Arm title	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID
Arm description:	
Phase 1b Dose Level 3: 10 mg/kg TRC105 weekly during cycle 1 then 15 mg/kg TRC105 every two weeks beginning in cycle 2 in combination with 5 mg Axitinib twice daily	
Arm type	Experimental
Investigational medicinal product name	Axitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
5mg tablets twice daily	
Investigational medicinal product name	TRC 105
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
10 mg/kg TRC105 weekly during cycle 1 then 15 mg/kg TRC105 every two weeks beginning in cycle 2	

Number of subjects in period 1	P2 Arm A: 5 mg Axitinib BID	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Started	75	75	3
Completed	74	73	3
Not completed	1	2	0
Randomized not enrolled	1	2	-

Number of subjects in period 1	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID
Started	15	5
Completed	15	5
Not completed	0	0
Randomized not enrolled	-	-

Baseline characteristics

Reporting groups

Reporting group title	P2 Arm A: 5 mg Axitinib BID
Reporting group description:	
Phase 2 Arm A: 5 mg Axitinib twice daily	
Reporting group title	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Reporting group description:	
Phase 2 Arm B: 10 mg/kg TRC105 weekly + 5 mg Axitinib twice daily	
Reporting group title	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Reporting group description:	
Phase 1b Dose Level 1: 8 mg/kg TRC105 weekly in combination with 5 mg Axitinib twice daily	
Reporting group title	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Reporting group description:	
Phase 1b Dose Level 2: 10 mg/kg TRC105 weekly in combination with 5 mg Axitinib twice daily	
Reporting group title	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID
Reporting group description:	
Phase 1b Dose Level 3: 10 mg/kg TRC105 weekly during cycle 1 then 15 mg/kg TRC105 every two weeks beginning in cycle 2 in combination with 5 mg Axitinib twice daily	

Reporting group values	P2 Arm A: 5 mg Axitinib BID	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Number of subjects	75	75	3
Age categorical			
All patients who received at least a portion of a dose of TRC105 or axitinib			
Units: Subjects			
Adults (18-64 years)	35	43	0
From 65-84 years	40	32	3
Gender categorical			
All patients who received at least a portion of a dose of TRC105 or axitinib			
Units: Subjects			
Female	18	26	0
Male	57	49	3
Race/Ethnicity			
All patients who received at least a portion of a dose of TRC105 or axitinib			
Units: Subjects			
Caucasian	70	71	3
Hispanic or Latino	5	1	0
American Indian or Alaska Native	0	2	0
Native Hawaiian or other Pacific Islander	0	1	0
Region of Enrollment			
All patients who received at least a portion of a dose of TRC105 or axitinib			
Units: Subjects			
Hungary	11	10	0
United States	56	59	3
Czechia	8	5	0
United Kingdom	0	1	0

Reporting group values	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID	Total
Number of subjects	15	5	173
Age categorical			
All patients who received at least a portion of a dose of TRC105 or axitinib			
Units: Subjects			
Adults (18-64 years)	13	2	93
From 65-84 years	2	3	80
Gender categorical			
All patients who received at least a portion of a dose of TRC105 or axitinib			
Units: Subjects			
Female	2	2	48
Male	13	3	125
Race/Ethnicity			
All patients who received at least a portion of a dose of TRC105 or axitinib			
Units: Subjects			
Caucasian	12	5	161
Hispanic or Latino	3	0	9
American Indian or Alaska Native	0	0	2
Native Hawaiian or other Pacific Islander	0	0	1
Region of Enrollment			
All patients who received at least a portion of a dose of TRC105 or axitinib			
Units: Subjects			
Hungary	0	0	21
United States	15	5	138
Czechia	0	0	13
United Kingdom	0	0	1

End points

End points reporting groups

Reporting group title	P2 Arm A: 5 mg Axitinib BID
Reporting group description:	
Phase 2 Arm A: 5 mg Axitinib twice daily	
Reporting group title	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Reporting group description:	
Phase 2 Arm B: 10 mg/kg TRC105 weekly + 5 mg Axitinib twice daily	
Reporting group title	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Reporting group description:	
Phase 1b Dose Level 1: 8 mg/kg TRC105 weekly in combination with 5 mg Axitinib twice daily	
Reporting group title	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Reporting group description:	
Phase 1b Dose Level 2: 10 mg/kg TRC105 weekly in combination with 5 mg Axitinib twice daily	
Reporting group title	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID
Reporting group description:	
Phase 1b Dose Level 3: 10 mg/kg TRC105 weekly during cycle 1 then 15 mg/kg TRC105 every two weeks beginning in cycle 2 in combination with 5 mg Axitinib twice daily	

Primary: Phase 1b: Number of Patients with DLT

End point title	Phase 1b: Number of Patients with DLT ^{[1][2]}
End point description:	
Phase 1b: For dose limiting toxicity (DLT) evaluation, severity (grade) was classified according to common terminology criteria for adverse events version 4.0 (CTCAE v4.0).	
Patients who discontinued the study prior to completing the DLT evaluation period were not evaluable.	
End point type	Primary
End point timeframe:	
12 Months	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: In Phase 1b there were no dose limiting toxicities.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: For Phase 2 the number of patients with DLT was not measured.

End point values	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	15	5	
Units: Participants	0	0	0	

Statistical analyses

Primary: Phase 2: Progression free survival (PFS) of patients with RCC

End point title	Phase 2: Progression free survival (PFS) of patients with RCC ^[3]
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End point description:

Median progression free survival (PFS) of patients with advanced or metastatic RCC by RECIST 1.1. Progression is defined using Response Evaluation Criteria In Solid Tumors Criteria (RECIST v1.1), as a 20% increase in the sum of the longest diameter of target lesions, or a measurable increase in a non-target lesion, or the appearance of new lesions.

For Phase 2 all randomized patients were included in the efficacy population.

End point type	Primary
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End point timeframe:

15 Months

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: PFS was not measured in Phase 1b.

End point values	P2 Arm A: 5 mg Axitinib BID	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	75		
Units: Months				
median (confidence interval 95%)	11.4 (5.8 to 13)	6.7 (5.6 to 13.1)		

Statistical analyses

Statistical analysis title	Comparative
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Statistical analysis description:

PFS comparison between Arm A and Arm B.

Comparison groups	P2 Arm A: 5 mg Axitinib BID v P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.1
Method	Logrank

Secondary: Phase 1b & 2: Response Rate of patients with RCC

End point title	Phase 1b & 2: Response Rate of patients with RCC
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End point description:

Number of patients with partial response (PR) or complete response (CR) by RECIST 1.1 criteria. Per Response Evaluation Criteria in Solid Tumors Criteria RECIST v1.1 for target lesions and assessed by MRI: Complete Response (CR), Disappearance of all target lesions; Partial Response (PR), ≥30% decrease in the sum of the longest diameter of target lesions; Overall Response (OR) = CR + PR. For Phase 1b patients with screening and at least 1 on study scan were included in the efficacy population. For Phase 2 all randomized patients were included in the efficacy population. Patients without a baseline scan and at least 1 on study scan were excluded from analysis.

End point type	Secondary
End point timeframe:	
15 Months	

End point values	P2 Arm A: 5 mg Axitinib BID	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	75	75	3	14
Units: Participants	22	23	0	5

End point values	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: Participants	0			

Statistical analyses

Statistical analysis title	Comparative
Statistical analysis description:	
Response rate by RECIST 1.1 criteria.	
Comparison groups	P2 Arm A: 5 mg Axitinib BID v P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID v P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID v P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID v P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	other ^[4]
P-value	≤ 0.1
Method	Chi-squared test

Notes:

[4] - Response rate by RECIST in Phase 1b patients (descriptive) and in Phase 2 patients (superiority).

Secondary: Phase 2: Overall Response Rate of patients with RCC by Choi

End point title	Phase 2: Overall Response Rate of patients with RCC by Choi ^[5]
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End point description:

Overall response (OR) rate is the number of patients with partial response (PR) or complete response (CR) by Choi Criteria. Per Choi criteria for target lesions and assessed by MRI: Complete Response (CR), Disappearance of all target lesions; Partial Response (PR), A decrease in size ≥ 10% or a decrease in tumor attenuation (Hounsfield units) ≥ 15% on CT and no new lesions; Overall Response (OR) = CR + PR.

For Phase 2 all randomized patients were included in the efficacy population. Patients without a baseline

scan and at least 1 on study scan were excluded from analysis.

End point type	Secondary
End point timeframe:	
15 Months	

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: For Phase 1b Overall Response Rate of patients with RCC by Choi was not measured.

End point values	P2 Arm A: 5 mg Axitinib BID	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	75	75		
Units: Participants	50	50		

Statistical analyses

Statistical analysis title	Comparative
Statistical analysis description:	
The primary endpoint for efficacy is PFS.	
Comparison groups	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID v P2 Arm A: 5 mg Axitinib BID
Number of subjects included in analysis	150
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.1 [6]
Method	Chi-square

Notes:

[6] - One-sided test

Secondary: Phase 1b & 2: Trough concentrations of TRC105 by Dose Level in Phase 1b

End point title	Phase 1b & 2: Trough concentrations of TRC105 by Dose Level in Phase 1b ^[7]
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End point description:

Trough Serum TRC105 concentrations at steady state (cycle 2 day 15) were measured using validated ELISA methods.

In Phase 1b patients with a predose sample collected at cycle 2 day 15 were averaged. Patients who missed a dose of TRC105 prior to cycle 2 day 15 were excluded from the analysis. Additional Phase 1b PK analysis beyond steady state concentration at cycle 2 day 15 were not performed. Samples collected in the phase 2 portion of the study were not analyzed.

End point type	Secondary
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End point timeframe:

2.5 months (cycle 2 day 15)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The study was terminated due to lack of efficacy and samples collected in the phase 2 portion of the study were not analyzed.

End point values	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	13	5	
Units: ng/mL				
arithmetic mean (standard deviation)	27650 (± 39103)	140022 (± 45403.1)	54375 (± 23546.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b & 2: Number of patients with development of immunogenicity antibodies.

End point title	Phase 1b & 2: Number of patients with development of immunogenicity antibodies. ^[8]
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End point description:

Anti-product antibody concentration were measured using validated ELISA methods.

Patients must have had a baseline and on study assessment of immunogenicity and their baseline must have been negative. Samples collected in the phase 2 portion of the study were not analyzed.

End point type	Secondary
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End point timeframe:

12 Months

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The study was terminated early due to lack of efficacy and samples collected in the phase 2 portion of the study were not analyzed.

End point values	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	5	5	
Units: Participants	1	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

2 years, 6 months. Only patients who received at least a portion of a dose of TRC105 and/or Axitinib have been included in the analysis population.

Adverse event reporting additional description:

Any untoward or unfavorable medical occurrence in a participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participant's participation in the research, whether or not considered related to the participant's participation in the research.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	4.0

Reporting groups

Reporting group title	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID
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Reporting group description:

Phase 1b Dose Level 1: 8 mg/kg TRC105 weekly in combination with 5 mg Axitinib twice daily

Reporting group title	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
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Reporting group description:

Phase 1b Dose Level 2: 10 mg/kg TRC105 weekly in combination with 5 mg Axitinib twice daily

Reporting group title	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID
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Reporting group description:

Phase 1b Dose Level 3: 10 mg/kg TRC105 weekly during cycle 1 then 15 mg/kg TRC105 every two weeks beginning in cycle 2 in combination with 5 mg Axitinib twice daily

Reporting group title	P2 Arm A: 5 mg Axitinib BID
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Reporting group description:

Phase 2 Arm A: 5 mg Axitinib twice daily

Reporting group title	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID
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Reporting group description:

Phase 2 Arm B: 10 mg/kg TRC105 weekly + 5 mg Axitinib twice daily

Serious adverse events	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	4 / 15 (26.67%)	3 / 5 (60.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bronchial Neoplasm			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease Progression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ Failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion Related Reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Heart Failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage Intracranial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior Reversible Encephalopathy Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal Vein Occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder Perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Ulcer Haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic Perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Liver Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Biliary Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Enterococcal Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	2 / 5 (40.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	P2 Arm A: 5 mg Axitinib BID	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	
Total subjects affected by serious adverse events			
subjects affected / exposed	27 / 74 (36.49%)	28 / 73 (38.36%)	
number of deaths (all causes)	3	3	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bronchial Neoplasm			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease Progression			
subjects affected / exposed	0 / 74 (0.00%)	4 / 73 (5.48%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 4	
Fatigue			

subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ Failure			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (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			
Pelvic Pain			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Haemorrhage			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (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	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pleural Effusion			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Failure			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vomiting			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion Related Reaction			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (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	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal Fracture			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac disorders			
Acute Heart Failure			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myocardial Infarction			
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage Intracranial			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Posterior Reversible Encephalopathy Syndrome			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 74 (1.35%)	5 / 73 (6.85%)	
occurrences causally related to treatment / all	0 / 1	4 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Retinal Vein Occlusion			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder Perforation			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			

subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (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 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal Ulcer Haemorrhage			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic Perforation			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Perforation			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Haemorrhage			
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			

subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Liver Injury			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular Weakness			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Biliary Tract Infection			

subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Infection			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal Infection			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			

subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	P1b: 8 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	P1b: 10 mg/kg Wkly/15 mg/kg q2wks TRC105 + 5 mg Axitinib BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	15 / 15 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Benign Neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Breast Cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin Papilloma			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Arteriosclerosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hot Flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	2 / 3 (66.67%)	4 / 15 (26.67%)	4 / 5 (80.00%)
occurrences (all)	5	8	6
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	1 / 5 (20.00%)
occurrences (all)	0	1	1

Orthostatic Hypotension subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Thrombophlebitis Superficial subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Surgical and medical procedures			
Colostomy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Tooth Extraction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Preventive Surgery subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	0 / 5 (0.00%) 0
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	3 / 3 (100.00%) 5	2 / 15 (13.33%) 3	0 / 5 (0.00%) 0
Catheter Site Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Catheter Site Swelling subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Chest Discomfort subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	0 / 5 (0.00%) 0
Chest Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 15 (13.33%) 4	0 / 5 (0.00%) 0
Chills subjects affected / exposed occurrences (all)	3 / 3 (100.00%) 4	1 / 15 (6.67%) 1	1 / 5 (20.00%) 1
Drug Intolerance			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Facial Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	9 / 15 (60.00%)	4 / 5 (80.00%)
occurrences (all)	4	28	6
Feeling Cold			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Feeling Hot			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General Physical Health Deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Infusion Site Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion Site Extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection Site Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection Site Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection Site Mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Local Swelling			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Medical Device Site Bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
subjects affected / exposed	1 / 3 (33.33%)	7 / 15 (46.67%)	0 / 5 (0.00%)
occurrences (all)	1	9	0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 3 (66.67%)	4 / 15 (26.67%)	1 / 5 (20.00%)
occurrences (all)	8	5	1
Temperature Intolerance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gait Disturbance			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Immune system disorders			

Hypersensitivity subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Seasonal Allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Reproductive system and breast disorders			
Breast Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Erectile Dysfunction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Genital Discharge subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Gynaecomastia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Nipple Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Pelvic Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Prostatic Obstruction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Scrotal Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Vaginal Lesion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Vulvovaginal Pain			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Choking Sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 3 (33.33%)	5 / 15 (33.33%)	1 / 5 (20.00%)
occurrences (all)	1	6	1
Dry Throat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 3 (33.33%)	6 / 15 (40.00%)	3 / 5 (60.00%)
occurrences (all)	1	13	3
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Dyspnoea Exertional			
subjects affected / exposed	1 / 3 (33.33%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	4	2	0
Epistaxis			
subjects affected / exposed	2 / 3 (66.67%)	13 / 15 (86.67%)	5 / 5 (100.00%)
occurrences (all)	2	23	6
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Increased Upper Airway Secretion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Nasal Dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal Septum Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal Septum Perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal Septum Ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal Ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pleural Effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Productive Cough			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pulmonary Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Respiratory Tract Congestion			
subjects affected / exposed	1 / 3 (33.33%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Rhinitis Allergic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Sinus Congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sleep Apnoea Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper-airway Cough Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Confusional State			
subjects affected / exposed	1 / 3 (33.33%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Delirium			

subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	3 / 15 (20.00%)	1 / 5 (20.00%)
occurrences (all)	1	3	1
Mental Status Changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 3 (33.33%)	3 / 15 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	7	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Blood Amylase Increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Blood Bilirubin Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood Pressure Increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood Thyroid Stimulating Hormone Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood Thyroid Stimulating Hormone Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood Urea Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac Murmur			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epidermal Growth Factor Receptor Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Glucose Urine Present			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoglobin Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
International Normalised Ratio Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron Binding Capacity Total Decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase Increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	2	2	0
Liver Function Test Abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Liver Function Test Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mycobacterium Tuberculosis Complex Test Positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Red Blood Cells Urine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Transaminases Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin D Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 15 (20.00%)	2 / 5 (40.00%)
occurrences (all)	0	4	7
Weight Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

White Blood Cells Urine subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Food Intolerance subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 5	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Head Injury subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Incisional Hernia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Infusion Related Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 15 (20.00%) 3	0 / 5 (0.00%) 0
Joint Injury subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Laceration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Limb Injury subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	0 / 5 (0.00%) 0
Lower Limb Fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post Procedural Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rib Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Road Traffic Accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin Abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sternal Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wound Complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wound Dehiscence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Acute Coronary Syndrome subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Angina Pectoris subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Arrhythmia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	0 / 5 (0.00%) 0
Bundle Branch Block Right subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Cardiac Disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Cardiac Failure subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Cardiac Failure Acute subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Coronary Artery Disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Coronary Artery Thrombosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Diastolic Dysfunction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Left Ventricular Dysfunction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0

Mitral Valve Incompetence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Pericardial Effusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Sinus Bradycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Sinus Tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Supraventricular Extrasystoles subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	1 / 5 (20.00%) 1
Tricuspid Valve Incompetence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Ventricular Extrasystoles subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Wandering Pacemaker subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	0 / 5 (0.00%) 0
Nervous system disorders Amnesia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Balance Disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Burning Sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular Accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disturbance In Attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	3 / 15 (20.00%)	1 / 5 (20.00%)
occurrences (all)	1	3	1
Dizziness Postural			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dyskinesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	3 / 3 (100.00%)	10 / 15 (66.67%)	2 / 5 (40.00%)
occurrences (all)	4	17	2
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	2 / 3 (66.67%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Memory Impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mental Impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolic Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuropathy Peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Paresis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal Cord Compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Speech Disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Ageusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	4 / 15 (26.67%)	1 / 5 (20.00%)
occurrences (all)	1	17	4

Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Microcytic Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Polycythaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemolytic Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Cerumen Impaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hearing Impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Tympanic Membrane Perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye Discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Periorbital Oedema			
subjects affected / exposed	0 / 3 (0.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retinal Vein Occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Vision Blurred			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Visual Impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ocular Hyperaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Abdominal Distension			
subjects affected / exposed	0 / 3 (0.00%)	3 / 15 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	5	0
Abdominal Hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	5 / 15 (33.33%)	1 / 5 (20.00%)
occurrences (all)	0	7	2
Abdominal Pain Lower			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain Upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal Tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anorectal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			

subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	5 / 15 (33.33%)	2 / 5 (40.00%)
occurrences (all)	2	7	2
Dental Caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	3 / 3 (100.00%)	11 / 15 (73.33%)	4 / 5 (80.00%)
occurrences (all)	8	32	14
Diverticulum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry Mouth			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Dyskinesia Oesophageal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Enteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Faecal Incontinence			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Faeces Discoloured			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Faeces Pale			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 3 (0.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Gingival Bleeding			
subjects affected / exposed	2 / 3 (66.67%)	7 / 15 (46.67%)	5 / 5 (100.00%)
occurrences (all)	3	11	5
Gingival Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Haematochezia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Haemorrhoidal Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Hiatus Hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Large Intestine Perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mesenteric Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth Ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	9 / 15 (60.00%)	4 / 5 (80.00%)
occurrences (all)	1	16	6
Oesophageal Ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral Discomfort			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral Mucosal Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Paraesthesia Oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peptic Ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periodontal Disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rectal Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Salivary Hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	3 / 5 (60.00%)
occurrences (all)	0	5	6
Swollen Tongue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	5 / 15 (33.33%)	4 / 5 (80.00%)
occurrences (all)	1	8	6
Duodenitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Impaired Gastric Emptying			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Periodontitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Bile Duct Stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gallbladder Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Liver Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Actinic Keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decubitus Ulcer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dermatitis Acneiform			
subjects affected / exposed	0 / 3 (0.00%)	3 / 15 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Dermatitis Bullous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Hyperhidrosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ingrowing Nail			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Livedo Reticularis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail Discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	2 / 3 (66.67%)	3 / 15 (20.00%)	0 / 5 (0.00%)
occurrences (all)	2	3	0
Palmar-plantar Erythrodysesthesia Syndrome			
subjects affected / exposed	1 / 3 (33.33%)	5 / 15 (33.33%)	2 / 5 (40.00%)
occurrences (all)	2	10	4
Palmoplantar Keratoderma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Photosensitivity Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 3 (33.33%)	3 / 15 (20.00%)	1 / 5 (20.00%)
occurrences (all)	1	4	1
Rash Erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Rash Macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-papular			
subjects affected / exposed	1 / 3 (33.33%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Rash Pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin Discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin Erosion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin Exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin Hyperpigmentation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Skin Ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Subcutaneous Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Swelling Face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Telangiectasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Bladder Spasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Glycosuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Micturition Urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Renal Failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urethral Meatus Stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Thyroid Disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 15 (13.33%) 3	0 / 5 (0.00%) 0
Back Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 15 (20.00%) 3	1 / 5 (20.00%) 2
Bone Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	0 / 5 (0.00%) 0
Flank Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Groin Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Inguinal Mass subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Joint Swelling subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Muscle Spasms subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 15 (13.33%) 2	0 / 5 (0.00%) 0
Muscular Weakness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	0 / 5 (0.00%) 0
Musculoskeletal Chest Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Musculoskeletal Pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Neck Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
subjects affected / exposed	0 / 3 (0.00%)	5 / 15 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	6	0
Pain In Jaw			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Pathological Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Plantar Fasciitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spondylolisthesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			

Anal Abscess			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dacryocanaliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea Infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fungal Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fungal Skin Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Gingival Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Incision Site Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Kidney Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lung Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymph Gland Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nail Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral Herpes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Otitis Externa			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Otitis Media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Skin Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Staphylococcal Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinea Cruris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinea Pedis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinea Versicolour			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth Abscess			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Tooth Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Upper Respiratory Infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	1 / 5 (20.00%) 1
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Urinary Tract Infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	3 / 5 (60.00%) 4
Vaginal Infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Viral Infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Vulvovaginal Mycotic Infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Wound Infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Nasal Vestibulitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	0 / 5 (0.00%) 0
Pneumonial Staphylococcal subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 15 (6.67%) 1	0 / 5 (0.00%) 0
Metabolism and nutrition disorders			
Cachexia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 15 (0.00%) 0	0 / 5 (0.00%) 0
Decreased Appetite subjects affected / exposed occurrences (all)	3 / 3 (100.00%) 3	5 / 15 (33.33%) 10	3 / 5 (60.00%) 4
Dehydration			

subjects affected / exposed	3 / 3 (100.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	5	3	0
Glucose Tolerance Impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 15 (13.33%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 15 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	6	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	5	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Hypomagnesaemia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 15 (13.33%)	1 / 5 (20.00%)
occurrences (all)	1	2	1
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	1 / 5 (20.00%)
occurrences (all)	0	1	2
Hypoproteinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 15 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 15 (6.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	P2 Arm A: 5 mg Axitinib BID	P2 Arm B: 10 mg/kg TRC105 Wkly + 5 mg Axitinib BID	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	71 / 74 (95.95%)	72 / 73 (98.63%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)	
occurrences (all)	0	3	
Benign Neoplasm			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Breast Cancer			

subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Skin Papilloma			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Aortic Aneurysm			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Arteriosclerosis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Deep Vein Thrombosis			
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)	
occurrences (all)	2	0	
Embolism			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Flushing			
subjects affected / exposed	0 / 74 (0.00%)	7 / 73 (9.59%)	
occurrences (all)	0	8	
Haematoma			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Haemorrhage			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Hot Flush			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	4	
Hyperaemia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	33 / 74 (44.59%)	26 / 73 (35.62%)	
occurrences (all)	61	47	

Hypotension subjects affected / exposed occurrences (all)	2 / 74 (2.70%) 2	7 / 73 (9.59%) 11	
Orthostatic Hypotension subjects affected / exposed occurrences (all)	1 / 74 (1.35%) 1	0 / 73 (0.00%) 0	
Thrombophlebitis Superficial subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	1 / 73 (1.37%) 1	
Surgical and medical procedures Colostomy subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	1 / 73 (1.37%) 1	
Tooth Extraction subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	1 / 73 (1.37%) 2	
Preventive Surgery subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	0 / 73 (0.00%) 0	
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	9 / 74 (12.16%) 9	6 / 73 (8.22%) 8	
Catheter Site Pain subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	1 / 73 (1.37%) 1	
Catheter Site Swelling subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	1 / 73 (1.37%) 1	
Chest Discomfort subjects affected / exposed occurrences (all)	1 / 74 (1.35%) 1	0 / 73 (0.00%) 0	
Chest Pain subjects affected / exposed occurrences (all)	4 / 74 (5.41%) 6	1 / 73 (1.37%) 1	
Chills			

subjects affected / exposed	7 / 74 (9.46%)	11 / 73 (15.07%)
occurrences (all)	9	13
Drug Intolerance		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Facial Pain		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Fatigue		
subjects affected / exposed	40 / 74 (54.05%)	42 / 73 (57.53%)
occurrences (all)	75	72
Feeling Cold		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Feeling Hot		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
General Physical Health Deterioration		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Influenza Like Illness		
subjects affected / exposed	3 / 74 (4.05%)	2 / 73 (2.74%)
occurrences (all)	3	3
Infusion Site Erythema		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Infusion Site Extravasation		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Injection Site Erythema		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Injection Site Haemorrhage		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Injection Site Mass		

subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Local Swelling		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Malaise		
subjects affected / exposed	4 / 74 (5.41%)	3 / 73 (4.11%)
occurrences (all)	4	3
Medical Device Site Bruise		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Mucosal Inflammation		
subjects affected / exposed	6 / 74 (8.11%)	10 / 73 (13.70%)
occurrences (all)	9	11
Non-Cardiac Chest Pain		
subjects affected / exposed	4 / 74 (5.41%)	3 / 73 (4.11%)
occurrences (all)	5	4
Oedema		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	2
Oedema Peripheral		
subjects affected / exposed	5 / 74 (6.76%)	5 / 73 (6.85%)
occurrences (all)	12	6
Pain		
subjects affected / exposed	2 / 74 (2.70%)	2 / 73 (2.74%)
occurrences (all)	2	2
Pyrexia		
subjects affected / exposed	4 / 74 (5.41%)	10 / 73 (13.70%)
occurrences (all)	4	10
Temperature Intolerance		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Thirst		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Gait Disturbance		

subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	0 / 73 (0.00%) 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Seasonal Allergy			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Breast Pain			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Erectile Dysfunction			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Genital Discharge			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Gynaecomastia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Nipple Pain			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Pelvic Pain			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Prostatic Obstruction			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Scrotal Pain			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Vaginal Lesion			

subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Vulvovaginal Pain			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Choking Sensation			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Cough			
subjects affected / exposed	15 / 74 (20.27%)	14 / 73 (19.18%)	
occurrences (all)	24	18	
Dry Throat			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Dysphonia			
subjects affected / exposed	27 / 74 (36.49%)	19 / 73 (26.03%)	
occurrences (all)	34	21	
Dyspnoea			
subjects affected / exposed	10 / 74 (13.51%)	12 / 73 (16.44%)	
occurrences (all)	18	15	
Dyspnoea Exertional			
subjects affected / exposed	3 / 74 (4.05%)	3 / 73 (4.11%)	
occurrences (all)	4	3	
Epistaxis			
subjects affected / exposed	5 / 74 (6.76%)	47 / 73 (64.38%)	
occurrences (all)	6	68	
Haemoptysis			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Hiccups			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Hypoxia			

subjects affected / exposed	1 / 74 (1.35%)	3 / 73 (4.11%)
occurrences (all)	1	6
Increased Upper Airway Secretion		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Nasal Congestion		
subjects affected / exposed	4 / 74 (5.41%)	6 / 73 (8.22%)
occurrences (all)	5	6
Nasal Dryness		
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	2
Nasal Septum Disorder		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Nasal Septum Perforation		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Nasal Septum Ulceration		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Nasal Ulcer		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Oropharyngeal Pain		
subjects affected / exposed	6 / 74 (8.11%)	13 / 73 (17.81%)
occurrences (all)	7	14
Pleural Effusion		
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	3
Productive Cough		
subjects affected / exposed	3 / 74 (4.05%)	4 / 73 (5.48%)
occurrences (all)	3	6
Pulmonary Embolism		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Respiratory Tract Congestion		

subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Rhinitis Allergic			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Rhinorrhoea			
subjects affected / exposed	2 / 74 (2.70%)	5 / 73 (6.85%)	
occurrences (all)	2	5	
Sinus Congestion			
subjects affected / exposed	2 / 74 (2.70%)	2 / 73 (2.74%)	
occurrences (all)	2	2	
Sleep Apnoea Syndrome			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	2	
Tachypnoea			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Upper Respiratory Tract Inflammation			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Upper-airway Cough Syndrome			
subjects affected / exposed	1 / 74 (1.35%)	3 / 73 (4.11%)	
occurrences (all)	1	3	
Wheezing			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	2	0	
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)	
occurrences (all)	1	2	
Anxiety			
subjects affected / exposed	5 / 74 (6.76%)	2 / 73 (2.74%)	
occurrences (all)	6	2	
Confusional State			

subjects affected / exposed	1 / 74 (1.35%)	4 / 73 (5.48%)	
occurrences (all)	1	5	
Delirium			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	2	
Depression			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	6 / 74 (8.11%)	5 / 73 (6.85%)	
occurrences (all)	7	5	
Mental Status Changes			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Alanine Aminotransferase Increased			
subjects affected / exposed	4 / 74 (5.41%)	4 / 73 (5.48%)	
occurrences (all)	4	7	
Aspartate Aminotransferase Increased			
subjects affected / exposed	7 / 74 (9.46%)	5 / 73 (6.85%)	
occurrences (all)	9	7	
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	2 / 74 (2.70%)	7 / 73 (9.59%)	
occurrences (all)	2	7	
Blood Amylase Increased			
subjects affected / exposed	7 / 74 (9.46%)	2 / 73 (2.74%)	
occurrences (all)	15	7	
Blood Bilirubin Increased			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Blood Creatinine Increased			

subjects affected / exposed	9 / 74 (12.16%)	5 / 73 (6.85%)
occurrences (all)	14	9
Blood Pressure Increased		
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)
occurrences (all)	4	5
Blood Thyroid Stimulating Hormone Decreased		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Blood Thyroid Stimulating Hormone Increased		
subjects affected / exposed	4 / 74 (5.41%)	5 / 73 (6.85%)
occurrences (all)	6	8
Blood Urea Increased		
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)
occurrences (all)	2	0
Cardiac Murmur		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Electrocardiogram QT Prolonged		
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)
occurrences (all)	0	3
Epidermal Growth Factor Receptor Increased		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Gamma-Glutamyltransferase Increased		
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	7
Glucose Urine Present		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Haemoglobin Increased		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
International Normalised Ratio Increased		

subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Iron Binding Capacity Total Decreased		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Lipase Increased		
subjects affected / exposed	5 / 74 (6.76%)	2 / 73 (2.74%)
occurrences (all)	5	3
Liver Function Test Abnormal		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	2	0
Liver Function Test Increased		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Lymphocyte Count Decreased		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Mycobacterium Tuberculosis Complex Test Positive		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Red Blood Cells Urine		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Transaminases Increased		
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)
occurrences (all)	3	0
Vitamin D Decreased		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Weight Decreased		
subjects affected / exposed	17 / 74 (22.97%)	27 / 73 (36.99%)
occurrences (all)	41	68
Weight Increased		

subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
White Blood Cell Count Decreased			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
White Blood Cells Urine			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Food Intolerance			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Gout			
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)	
occurrences (all)	2	1	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Fall			
subjects affected / exposed	3 / 74 (4.05%)	4 / 73 (5.48%)	
occurrences (all)	4	5	
Head Injury			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Incisional Hernia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Infusion Related Reaction			
subjects affected / exposed	0 / 74 (0.00%)	19 / 73 (26.03%)	
occurrences (all)	0	21	
Joint Injury			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Laceration			

subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Limb Injury		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Lower Limb Fracture		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	2
Muscle Strain		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Post Procedural Discomfort		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Procedural pain		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Rib Fracture		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Road Traffic Accident		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Skin Abrasion		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Sternal Fracture		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Thermal Burn		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Wound		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Wound Complication		

subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Wound Dehiscence			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Angina Pectoris			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Arrhythmia			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Bradycardia			
subjects affected / exposed	3 / 74 (4.05%)	0 / 73 (0.00%)	
occurrences (all)	3	0	
Bundle Branch Block Right			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Cardiac Disorder			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Cardiac Failure			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Cardiac Failure Acute			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Coronary Artery Disease			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Coronary Artery Thrombosis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	

Diastolic Dysfunction		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Left Ventricular Dysfunction		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Mitral Valve Incompetence		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Pericardial Effusion		
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)
occurrences (all)	1	2
Sinus Bradycardia		
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)
occurrences (all)	1	2
Sinus Tachycardia		
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)
occurrences (all)	2	1
Supraventricular Extrasystoles		
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)
occurrences (all)	1	1
Tachycardia		
subjects affected / exposed	1 / 74 (1.35%)	5 / 73 (6.85%)
occurrences (all)	1	6
Tricuspid Valve Incompetence		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Ventricular Extrasystoles		
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)
occurrences (all)	0	3
Wandering Pacemaker		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Palpitations		
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0

Nervous system disorders			
Amnesia			
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)	
occurrences (all)	2	0	
Balance Disorder			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Burning Sensation			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Cerebrovascular Accident			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Cognitive Disorder			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Convulsion			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Disturbance In Attention			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Dizziness			
subjects affected / exposed	9 / 74 (12.16%)	10 / 73 (13.70%)	
occurrences (all)	10	11	
Dizziness Postural			
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)	
occurrences (all)	2	0	
Dysaesthesia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	4	
Dysgeusia			
subjects affected / exposed	9 / 74 (12.16%)	10 / 73 (13.70%)	
occurrences (all)	9	12	
Dyskinesia			

subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Encephalopathy		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Headache		
subjects affected / exposed	12 / 74 (16.22%)	47 / 73 (64.38%)
occurrences (all)	18	88
Hyperaesthesia		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Hypersomnia		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Hypoaesthesia		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Hypotonia		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Lethargy		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Memory Impairment		
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	3
Mental Impairment		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Metabolic Encephalopathy		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Migraine		
subjects affected / exposed	0 / 74 (0.00%)	5 / 73 (6.85%)
occurrences (all)	0	8
Neuropathy Peripheral		

subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)
occurrences (all)	2	0
Paraesthesia		
subjects affected / exposed	3 / 74 (4.05%)	2 / 73 (2.74%)
occurrences (all)	3	2
Paresis		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Peripheral Sensory Neuropathy		
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)
occurrences (all)	2	2
Presyncope		
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)
occurrences (all)	1	2
Sciatica		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Sinus Headache		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	2
Spinal Cord Compression		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Syncope		
subjects affected / exposed	2 / 74 (2.70%)	3 / 73 (4.11%)
occurrences (all)	2	3
Tremor		
subjects affected / exposed	3 / 74 (4.05%)	1 / 73 (1.37%)
occurrences (all)	3	1
Somnolence		
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0
Speech Disorder		
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0
Ageusia		

subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	0 / 73 (0.00%) 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	12 / 74 (16.22%)	16 / 73 (21.92%)	
occurrences (all)	16	69	
Leukocytosis			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	4	
Leukopenia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	3	
Microcytic Anaemia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Neutropenia			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	3	2	
Polycythaemia			
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)	
occurrences (all)	3	1	
Thrombocytosis			
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)	
occurrences (all)	0	4	
Haemolytic Anaemia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Cerumen Impaction			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	2	
Ear Discomfort			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Ear Pain			

subjects affected / exposed	2 / 74 (2.70%)	3 / 73 (4.11%)	
occurrences (all)	2	3	
Hearing Impaired			
subjects affected / exposed	2 / 74 (2.70%)	2 / 73 (2.74%)	
occurrences (all)	2	2	
Hypoacusis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Tinnitus			
subjects affected / exposed	1 / 74 (1.35%)	3 / 73 (4.11%)	
occurrences (all)	1	3	
Tympanic Membrane Perforation			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Ear Haemorrhage			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Cataract			
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)	
occurrences (all)	2	0	
Eye Discharge			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Eye Pain			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Lacrimation increased			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Periorbital Oedema			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	

Photophobia			
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)	
occurrences (all)	1	2	
Retinal Vein Occlusion			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Vision Blurred			
subjects affected / exposed	4 / 74 (5.41%)	2 / 73 (2.74%)	
occurrences (all)	4	2	
Visual Impairment			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Ocular Hyperaemia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Abdominal Distension			
subjects affected / exposed	3 / 74 (4.05%)	1 / 73 (1.37%)	
occurrences (all)	4	1	
Abdominal Hernia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Abdominal Pain			
subjects affected / exposed	2 / 74 (2.70%)	10 / 73 (13.70%)	
occurrences (all)	16	11	
Abdominal Pain Lower			
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)	
occurrences (all)	4	2	
Abdominal Pain Upper			
subjects affected / exposed	5 / 74 (6.76%)	11 / 73 (15.07%)	
occurrences (all)	6	18	
Abdominal Tenderness			

subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)
occurrences (all)	1	1
Anorectal Discomfort		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Ascites		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Cheilitis		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	2
Colitis		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Constipation		
subjects affected / exposed	13 / 74 (17.57%)	21 / 73 (28.77%)
occurrences (all)	16	26
Dental Caries		
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)
occurrences (all)	0	3
Diarrhoea		
subjects affected / exposed	46 / 74 (62.16%)	42 / 73 (57.53%)
occurrences (all)	120	139
Diverticulum		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Dry Mouth		
subjects affected / exposed	7 / 74 (9.46%)	7 / 73 (9.59%)
occurrences (all)	7	7
Dyskinesia Oesophageal		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	2	0
Dyspepsia		
subjects affected / exposed	10 / 74 (13.51%)	6 / 73 (8.22%)
occurrences (all)	10	6
Dysphagia		

subjects affected / exposed	2 / 74 (2.70%)	2 / 73 (2.74%)
occurrences (all)	4	3
Enteritis		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Faecal Incontinence		
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)
occurrences (all)	1	2
Faeces Discoloured		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Faeces Pale		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Flatulence		
subjects affected / exposed	4 / 74 (5.41%)	7 / 73 (9.59%)
occurrences (all)	4	8
Gastritis		
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)
occurrences (all)	2	1
Gastrointestinal Pain		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Gastrooesophageal Reflux Disease		
subjects affected / exposed	1 / 74 (1.35%)	3 / 73 (4.11%)
occurrences (all)	2	3
Gingival Bleeding		
subjects affected / exposed	3 / 74 (4.05%)	25 / 73 (34.25%)
occurrences (all)	3	30
Gingival Pain		
subjects affected / exposed	1 / 74 (1.35%)	4 / 73 (5.48%)
occurrences (all)	1	5
Glossitis		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Glossodynia		

subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Haematemesis		
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	2
Haematochezia		
subjects affected / exposed	2 / 74 (2.70%)	2 / 73 (2.74%)
occurrences (all)	2	2
Haemorrhoidal Haemorrhage		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Haemorrhoids		
subjects affected / exposed	2 / 74 (2.70%)	4 / 73 (5.48%)
occurrences (all)	3	4
Hiatus Hernia		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Large Intestine Perforation		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Melaena		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Mesenteric Vein Thrombosis		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Mouth Haemorrhage		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Mouth Ulceration		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Nausea		
subjects affected / exposed	27 / 74 (36.49%)	38 / 73 (52.05%)
occurrences (all)	43	66
Oesophageal Ulcer		

subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Oesophagitis		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Oral Discomfort		
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)
occurrences (all)	1	1
Oral Disorder		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Oral Dysaesthesia		
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)
occurrences (all)	1	3
Oral Mucosal Erythema		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Oral Pain		
subjects affected / exposed	2 / 74 (2.70%)	8 / 73 (10.96%)
occurrences (all)	3	9
Paraesthesia Oral		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Peptic Ulcer		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Periodontal Disease		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Proctalgia		
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)
occurrences (all)	1	1
Rectal Haemorrhage		
subjects affected / exposed	1 / 74 (1.35%)	3 / 73 (4.11%)
occurrences (all)	1	3
Retching		

subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Salivary Hypersecretion			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Stomatitis			
subjects affected / exposed	8 / 74 (10.81%)	18 / 73 (24.66%)	
occurrences (all)	11	34	
Swollen Tongue			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Toothache			
subjects affected / exposed	3 / 74 (4.05%)	0 / 73 (0.00%)	
occurrences (all)	3	0	
Vomiting			
subjects affected / exposed	14 / 74 (18.92%)	30 / 73 (41.10%)	
occurrences (all)	23	57	
Duodenitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Impaired Gastric Emptying			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Periodontitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Bile Duct Stenosis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Cholelithiasis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Gallbladder Pain			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	

Hepatitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Liver Disorder			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Actinic Keratosis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Alopecia			
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)	
occurrences (all)	2	1	
Blister			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Decubitus Ulcer			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Dermatitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Dermatitis Acneiform			
subjects affected / exposed	2 / 74 (2.70%)	4 / 73 (5.48%)	
occurrences (all)	2	5	
Dermatitis Bullous			
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)	
occurrences (all)	0	6	
Dry Skin			
subjects affected / exposed	3 / 74 (4.05%)	4 / 73 (5.48%)	
occurrences (all)	3	4	
Erythema			

subjects affected / exposed	0 / 74 (0.00%)	6 / 73 (8.22%)
occurrences (all)	0	6
Hyperhidrosis		
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)
occurrences (all)	2	1
Hyperkeratosis		
subjects affected / exposed	3 / 74 (4.05%)	1 / 73 (1.37%)
occurrences (all)	3	1
Ingrowing Nail		
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)
occurrences (all)	3	0
Livedo Reticularis		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Nail Discolouration		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Night Sweats		
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	2
Palmar-plantar Erythrodysaesthesia Syndrome		
subjects affected / exposed	15 / 74 (20.27%)	18 / 73 (24.66%)
occurrences (all)	61	46
Palmoplantar Keratoderma		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Photosensitivity Reaction		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Pruritus		
subjects affected / exposed	2 / 74 (2.70%)	3 / 73 (4.11%)
occurrences (all)	2	6
Purpura		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1

Rash		
subjects affected / exposed	6 / 74 (8.11%)	12 / 73 (16.44%)
occurrences (all)	14	15
Rash Erythematous		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Rash Macular		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Rash Maculo-papular		
subjects affected / exposed	1 / 74 (1.35%)	6 / 73 (8.22%)
occurrences (all)	1	5
Rash Pruritic		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Rosacea		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Scab		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Skin Discolouration		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Skin Erosion		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Skin Exfoliation		
subjects affected / exposed	3 / 74 (4.05%)	0 / 73 (0.00%)
occurrences (all)	4	0
Skin Hyperpigmentation		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Skin Lesion		
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)
occurrences (all)	1	1

Skin Ulcer			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Subcutaneous Nodule			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Swelling Face			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Telangiectasia			
subjects affected / exposed	0 / 74 (0.00%)	5 / 73 (6.85%)	
occurrences (all)	0	5	
Petechiae			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)	
occurrences (all)	2	2	
Bladder Spasm			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Dysuria			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Glycosuria			
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)	
occurrences (all)	3	0	
Haematuria			
subjects affected / exposed	2 / 74 (2.70%)	8 / 73 (10.96%)	
occurrences (all)	2	8	
Hydronephrosis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Micturition Urgency			

subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Nephrolithiasis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Pollakiuria			
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)	
occurrences (all)	2	1	
Proteinuria			
subjects affected / exposed	15 / 74 (20.27%)	3 / 73 (4.11%)	
occurrences (all)	29	4	
Renal Failure			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	3	
Urethral Meatus Stenosis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Urinary Incontinence			
subjects affected / exposed	2 / 74 (2.70%)	2 / 73 (2.74%)	
occurrences (all)	2	2	
Urinary Retention			
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)	
occurrences (all)	1	2	
Urinary Tract Pain			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Incontinence			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Hypercalcaemia of malignancy			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	

Hyperthyroidism			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Hypothyroidism			
subjects affected / exposed	20 / 74 (27.03%)	17 / 73 (23.29%)	
occurrences (all)	25	18	
Thyroid Disorder			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	10 / 74 (13.51%)	8 / 73 (10.96%)	
occurrences (all)	18	15	
Back Pain			
subjects affected / exposed	17 / 74 (22.97%)	7 / 73 (9.59%)	
occurrences (all)	19	10	
Bone Pain			
subjects affected / exposed	0 / 74 (0.00%)	3 / 73 (4.11%)	
occurrences (all)	0	3	
Flank Pain			
subjects affected / exposed	2 / 74 (2.70%)	5 / 73 (6.85%)	
occurrences (all)	3	6	
Groin Pain			
subjects affected / exposed	2 / 74 (2.70%)	1 / 73 (1.37%)	
occurrences (all)	2	1	
Inguinal Mass			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Joint Swelling			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Muscle Spasms			
subjects affected / exposed	3 / 74 (4.05%)	2 / 73 (2.74%)	
occurrences (all)	3	2	
Muscular Weakness			

subjects affected / exposed	4 / 74 (5.41%)	4 / 73 (5.48%)
occurrences (all)	6	6
Musculoskeletal Chest Pain		
subjects affected / exposed	5 / 74 (6.76%)	3 / 73 (4.11%)
occurrences (all)	6	4
Musculoskeletal Pain		
subjects affected / exposed	6 / 74 (8.11%)	5 / 73 (6.85%)
occurrences (all)	6	6
Myalgia		
subjects affected / exposed	5 / 74 (6.76%)	7 / 73 (9.59%)
occurrences (all)	5	9
Neck Pain		
subjects affected / exposed	4 / 74 (5.41%)	2 / 73 (2.74%)
occurrences (all)	4	5
Osteoarthritis		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	5	0
Osteoporosis		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Pain In Extremity		
subjects affected / exposed	6 / 74 (8.11%)	14 / 73 (19.18%)
occurrences (all)	10	18
Pain In Jaw		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	2
Pathological Fracture		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Plantar Fasciitis		
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)
occurrences (all)	1	1
Spondylolisthesis		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Tendonitis		

subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Bronchitis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Candidiasis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Cellulitis			
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Cystitis			
subjects affected / exposed	1 / 74 (1.35%)	3 / 73 (4.11%)	
occurrences (all)	1	3	
Dacryocanaliculitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Diarrhoea Infectious			
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Folliculitis			
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)	
occurrences (all)	0	2	
Fungal Infection			
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Fungal Skin Infection			
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)	
occurrences (all)	2	2	

Furuncle		
subjects affected / exposed	0 / 74 (0.00%)	2 / 73 (2.74%)
occurrences (all)	0	2
Gingival Infection		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Incision Site Infection		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Influenza		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Kidney Infection		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Lung Infection		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Lymph Gland Infection		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Nail Infection		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Nasopharyngitis		
subjects affected / exposed	4 / 74 (5.41%)	3 / 73 (4.11%)
occurrences (all)	4	3
Oral Candidiasis		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Oral Herpes		
subjects affected / exposed	0 / 74 (0.00%)	4 / 73 (5.48%)
occurrences (all)	0	6
Otitis Externa		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1

Otitis Media		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Paronychia		
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)
occurrences (all)	2	0
Pharyngitis		
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)
occurrences (all)	1	1
Platelet Count Decreased		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Pneumonia		
subjects affected / exposed	1 / 74 (1.35%)	3 / 73 (4.11%)
occurrences (all)	1	3
Sepsis		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Sinusitis		
subjects affected / exposed	6 / 74 (8.11%)	3 / 73 (4.11%)
occurrences (all)	7	5
Skin Infection		
subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)
occurrences (all)	1	1
Staphylococcal Infection		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Tinea Cruris		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	2	0
Tinea Pedis		
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)
occurrences (all)	3	0
Tinea Versicolour		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1

Tooth Abscess subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	3 / 73 (4.11%) 4	
Tooth Infection subjects affected / exposed occurrences (all)	4 / 74 (5.41%) 4	1 / 73 (1.37%) 1	
Upper Respiratory Infection subjects affected / exposed occurrences (all)	8 / 74 (10.81%) 9	6 / 73 (8.22%) 9	
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	1 / 74 (1.35%) 1	1 / 73 (1.37%) 1	
Urinary Tract Infection subjects affected / exposed occurrences (all)	4 / 74 (5.41%) 5	5 / 73 (6.85%) 5	
Vaginal Infection subjects affected / exposed occurrences (all)	1 / 74 (1.35%) 1	1 / 73 (1.37%) 1	
Viral Infection subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	1 / 73 (1.37%) 1	
Vulvovaginal Mycotic Infection subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	1 / 73 (1.37%) 1	
Wound Infection subjects affected / exposed occurrences (all)	1 / 74 (1.35%) 1	0 / 73 (0.00%) 0	
Nasal Vestibulitis subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	0 / 73 (0.00%) 0	
Pneumonial Staphylococcal subjects affected / exposed occurrences (all)	0 / 74 (0.00%) 0	0 / 73 (0.00%) 0	
Metabolism and nutrition disorders Cachexia			

subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)
occurrences (all)	1	2
Decreased Appetite		
subjects affected / exposed	26 / 74 (35.14%)	21 / 73 (28.77%)
occurrences (all)	34	40
Dehydration		
subjects affected / exposed	7 / 74 (9.46%)	11 / 73 (15.07%)
occurrences (all)	15	19
Glucose Tolerance Impaired		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Hypercalcaemia		
subjects affected / exposed	5 / 74 (6.76%)	2 / 73 (2.74%)
occurrences (all)	13	2
Hypercholesterolaemia		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Hyperglycaemia		
subjects affected / exposed	6 / 74 (8.11%)	5 / 73 (6.85%)
occurrences (all)	14	14
Hyperkalaemia		
subjects affected / exposed	1 / 74 (1.35%)	2 / 73 (2.74%)
occurrences (all)	2	1
Hypernatraemia		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Hyperuricaemia		
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)
occurrences (all)	2	0
Hypoalbuminaemia		
subjects affected / exposed	3 / 74 (4.05%)	5 / 73 (6.85%)
occurrences (all)	5	7
Hypocalcaemia		
subjects affected / exposed	2 / 74 (2.70%)	2 / 73 (2.74%)
occurrences (all)	2	2
Hypoglycaemia		

subjects affected / exposed	1 / 74 (1.35%)	1 / 73 (1.37%)
occurrences (all)	1	2
Hypokalaemia		
subjects affected / exposed	4 / 74 (5.41%)	3 / 73 (4.11%)
occurrences (all)	8	4
Hypomagnesaemia		
subjects affected / exposed	2 / 74 (2.70%)	2 / 73 (2.74%)
occurrences (all)	2	2
Hyponatraemia		
subjects affected / exposed	5 / 74 (6.76%)	12 / 73 (16.44%)
occurrences (all)	5	17
Hypophosphataemia		
subjects affected / exposed	6 / 74 (8.11%)	3 / 73 (4.11%)
occurrences (all)	7	3
Hypoproteinaemia		
subjects affected / exposed	0 / 74 (0.00%)	1 / 73 (1.37%)
occurrences (all)	0	1
Hypovolaemia		
subjects affected / exposed	2 / 74 (2.70%)	0 / 73 (0.00%)
occurrences (all)	3	0
Type 2 Diabetes Mellitus		
subjects affected / exposed	1 / 74 (1.35%)	0 / 73 (0.00%)
occurrences (all)	1	0
Hyperphosphataemia		
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0
Hypertriglyceridaemia		
subjects affected / exposed	0 / 74 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was terminated early due to lack of efficacy therefore protein biomarkers (P1b and P2), PK (P2) and disease control rate at 16 weeks by RECIST 1.1 and Choi criteria were not analyzed.

Notes: