Clinical trial results:
A Pivotal Phase 2 Trial of Ponatinib (AP24534) in Patients with Refractory Chronic Myeloid Leukemia and Ph+ Acute Lymphoblastic Leukemia

Summary

EudraCT number	2010-020414-28
Trial protocol	GB SE DE FR BE NL ES IT
Global end of trial date	17 January 2019

Results information

Result version number	v1 (current)
This version publication date	02 February 2020
First version publication date	02 February 2020

Trial information

Trial identification

Sponsor protocol code	AP24534-10-201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01207440
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	40 Landsdowne Street, Cambridge, MA, United States, 02139
Public contact	Medical Director, Clinical Science, Takeda, +1 877-825-3327, clinicaltrialregistry@tpna.com
Scientific contact	Medical Director, Clinical Science, Takeda, +1 877-825-3327, clinicaltrialregistry@tpna.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	17 January 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 January 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to determine the efficacy of ponatinib in participants with chronic myeloid leukemia (CML) in chronic phase (CP), accelerated phase (AP) or blast phase (BP) or with philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) who either are resistant or intolerant to either dasatinib or nilotinib, or have the (T)hreonine-315-(I)soleucine (T315I) mutation.

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 September 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	96 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 12
Country: Number of subjects enrolled	Belgium: 7
Country: Number of subjects enrolled	Canada: 17
Country: Number of subjects enrolled	France: 55
Country: Number of subjects enrolled	Germany: 37
Country: Number of subjects enrolled	Italy: 39
Country: Number of subjects enrolled	Netherlands: 5
Country: Number of subjects enrolled	Korea, Republic of: 27
Country: Number of subjects enrolled	Singapore: 17
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	United Kingdom: 29
Country: Number of subjects enrolled	United States: 189
Worldwide total number of subjects	449
EEA total number of subjects	187

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	294
From 65 to 84 years	150
85 years and over	5

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 66 investigative sites in the Australia, Belgium, Canada, France, Germany, Italy, the Netherlands, Republic of Korea, Singapore, Spain, Sweden, the United Kingdom and the United States from 30 September 2010 to 17 January 2019.

Pre-assignment

Screening details:

Participants were assigned to 1 of 6 cohorts: chronic myeloid leukemia (CML) in chronic (CP), accelerated (AP), or blast phase (BP), or with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) who were resistant or intolerant (R-I) to either dasatinib or nilotinib or had (T)hreonine-315-(I)soleucine (T315I) mutation.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A: CP-CML R-I

Arm description:

CP-CML participants R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Arm type	Experimental
Investigational medicinal product name	Ponatinib
Investigational medicinal product code	
Other name	AP24534 Iclusig
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ponatinib tablets.

Arm title	Cohort B: CP-CML with T315I Mutation

Arm description:

CP-CML participants who had T315I mutation of breakpoint cluster region-Abelson complex (BCR-ABL) were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Arm type	Experimental
Investigational medicinal product name	Ponatinib
Investigational medicinal product code	
Other name	AP24534 Iclusig
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ponatinib tablets.

Arm title	Cohort C: AP-CML R-I

Arm description:

AP-CML R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until

disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Arm type	Experimental
Investigational medicinal product name	Ponatinib
Investigational medicinal product code	
Other name	AP24534 Iclusig
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ponatinib tablets.

Arm title	Cohort D: AP-CML with T315I Mutation

Arm description:

AP-CML participants who had T315I mutation of BCR-ABL were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Arm type	Experimental
Investigational medicinal product name	Ponatinib
Investigational medicinal product code	
Other name	AP24534 Iclusig
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ponatinib tablets.

Arm title	Cohort E: BP-CML/Ph+ ALL R-I

Arm description:

BP-CML or Ph+ ALL R-I to dasatinib or nilotinib or Ph+ ALL R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Arm type	Experimental
Investigational medicinal product name	Ponatinib
Investigational medicinal product code	
Other name	AP24534 Iclusig
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ponatinib tablets.

Arm title	Cohort F: BP-CML or Ph+ ALL with T315I Mutation

Arm description:

BP-CML or Ph+ ALL participants who had T315I mutation of BCR-ABL were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Arm type	Experimental
Investigational medicinal product name	Ponatinib
Investigational medicinal product code	
Other name	AP24534 Iclusig
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ponatinib tablets.

Arm title	Unassigned to Cohorts A-F

Arm description:

Participants who were not assigned to any of the cohorts and have no T315I mutation at study entry and were not resistant or intolerant to dasatinib or nilotinib, administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Arm type	Experimental
Investigational medicinal product name	Ponatinib
Investigational medicinal product code	
Other name	AP24534 Iclusig
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ponatinib tablets.

Number of subjects in period 1	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation	Cohort C: AP-CML R-I
Started	203	64	65
Completed	0	0	0
Not completed	203	64	65
Adverse event, serious fatal	6	3	2
Terminated by Sponsor	69	19	12
Non-compliance with Study Drug	3	-	1
Physician decision	6	5	5
Consent withdrawn by subject	29	4	5
Adverse event, non-fatal	46	11	7
Reason Not Specified	10	10	7
Progressive Disease	19	10	19
Lost to follow-up	-	-	2
Lack of efficacy	13	2	5
Protocol deviation	2	-	-

Number of subjects in period 1	Cohort D: AP-CML with T315I Mutation	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation
Started	18	48	46
Completed	0	0	0
Not completed	18	48	46
Adverse event, serious fatal	2	7	5
Terminated by Sponsor	2	3	-
Non-compliance with Study Drug	-	-	-
Physician decision	-	1	-
Consent withdrawn by subject	3	2	2
Adverse event, non-fatal	2	6	6

Reason Not Specified	-	4	3
Progressive Disease	7	23	27
Lost to follow-up	1	-	-
Lack of efficacy	1	2	3
Protocol deviation	-	-	-

Number of subjects in period 1	Unassigned to Cohorts A-F
Started	5
Completed	0
Not completed	5
Adverse event, serious fatal	1
Terminated by Sponsor	2
Non-compliance with Study Drug	-
Physician decision	-
Consent withdrawn by subject	-
Adverse event, non-fatal	2
Reason Not Specified	-
Progressive Disease	-
Lost to follow-up	-
Lack of efficacy	-
Protocol deviation	-

Baseline characteristics

Reporting groups	
Reporting group title	Cohort A: CP-CML R-I
Reporting group description:	
CP-CML participants R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).	
Reporting group title	Cohort B: CP-CML with T315I Mutation
Reporting group description:	
CP-CML participants who had T315I mutation of breakpoint cluster region-Abelson complex (BCR-ABL) were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).	
Reporting group title	Cohort C: AP-CML R-I
Reporting group description:	
AP-CML R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).	
Reporting group title	Cohort D: AP-CML with T315I Mutation
Reporting group description:	
AP-CML participants who had T315I mutation of BCR-ABL were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).	
Reporting group title	Cohort E: BP-CML/Ph+ ALL R-I
Reporting group description:	
BP-CML or Ph+ ALL R-I to dasatinib or nilotinib or Ph+ ALL R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).	
Reporting group title	Cohort F: BP-CML or Ph+ ALL with T315I Mutation
Reporting group description:	
BP-CML or Ph+ ALL participants who had T315I mutation of BCR-ABL were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).	
Reporting group title	Unassigned to Cohorts A-F
Reporting group description:	
Participants who were not assigned to any of the cohorts and have no T315I mutation at study entry and were not resistant or intolerant to dasatinib or nilotinib, administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).	

Reporting group values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation	Cohort C: AP-CML R-I
Number of subjects	203	64	65
Age categorical			
Units: Subjects			
Age Continuous			
Units: years			
median	61.0	52.0	60.0
full range (min-max)	22 to 94	18 to 87	23 to 82

Sex: Female, Male Units: Subjects			
Female	108	16	40
Male	95	48	25
Race/Ethnicity, Customized Units: Subjects			
American Indian/Alaska native	1	0	1
Asian	17	14	8
Black/African American	7	4	7
White	174	42	47
Unknown	3	3	2
Other	1	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	13	8	6
Not Hispanic or Latino	190	56	59
Unknown or Not Reported	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status (PS)			
ECOG-PS measured on-therapy assessed participant's performance status on 5 point scale: 0=Fully active/able to carry on all pre-disease activities without restriction; 1=restricted in physically strenuous activity, ambulatory/able to carry out light or sedentary work; 2=ambulatory (>50% of waking hrs), capable of all self care, unable to carry out any work activities; 3=capable of only limited self care, confined to bed/chair >50% of waking hrs; 4=completely disabled, cannot carry on any self care, totally confined to bed/chair; 5=dead.			
Units: Subjects			
ECOG=0	139	47	33
ECOG=1	60	17	25
ECOG=2	4	0	7
Missing ECOG Data	0	0	0
Time From Diagnosis to First Dose Units: years			
median	7.85	4.78	7.13
full range (min-max)	0.45 to 27.43	1.16 to 19.49	0.33 to 28.47

Reporting group values	Cohort D: AP-CML with T315I Mutation	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation
Number of subjects	18	48	46
Age categorical Units: Subjects			
Age Continuous Units: years			
median	54.0	54.0	56.0
full range (min-max)	24 to 78	18 to 74	18 to 80
Sex: Female, Male Units: Subjects			
Female	7	17	20
Male	11	31	26
Race/Ethnicity, Customized Units: Subjects			
American Indian/Alaska native	0	0	0
Asian	3	8	7

Black/African American	5	1	1
White	9	39	38
Unknown	0	0	0
Other	1	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	2	12
Not Hispanic or Latino	17	46	34
Unknown or Not Reported	0	0	0
Eastern Cooperative Oncology Group (ECOG) Performance Status (PS)			
ECOG-PS measured on-therapy assessed participant's performance status on 5 point scale: 0=Fully active/able to carry on all pre-disease activities without restriction; 1=restricted in physically strenuous activity, ambulatory/able to carry out light or sedentary work; 2=ambulatory (>50% of waking hrs), capable of all self care, unable to carry out any work activities; 3=capable of only limited self care, confined to bed/chair >50% of waking hrs; 4=completely disabled, cannot carry on any self care, totally confined to bed/chair; 5=dead.			
Units: Subjects			
ECOG=0	12	15	16
ECOG=1	6	20	19
ECOG=2	0	12	11
Missing ECOG Data	0	1	0
Time From Diagnosis to First Dose			
Units: years			
median	6.61	3.96	1.63
full range (min-max)	1.17 to 15.90	0.62 to 27.21	0.46 to 14.14

Reporting group values	Unassigned to Cohorts A-F	Total	
Number of subjects	5	449	
Age categorical			
Units: Subjects			
Age Continuous			
Units: years			
median	63.0		
full range (min-max)	51 to 71	-	
Sex: Female, Male			
Units: Subjects			
Female	3	211	
Male	2	238	
Race/Ethnicity, Customized			
Units: Subjects			
American Indian/Alaska native	0	2	
Asian	2	59	
Black/African American	0	25	
White	3	352	
Unknown	0	8	
Other	0	3	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	42	
Not Hispanic or Latino	5	407	

Unknown or Not Reported	0	0	
Eastern Cooperative Oncology Group (ECOG) Performance Status (PS)			
ECOG-PS measured on-therapy assessed participant's performance status on 5 point scale: 0=Fully active/able to carry on all pre-disease activities without restriction; 1=restricted in physically strenuous activity, ambulatory/able to carry out light or sedentary work; 2=ambulatory (>50% of waking hrs), capable of all self care, unable to carry out any work activities; 3=capable of only limited self care, confined to bed/chair >50% of waking hrs; 4=completely disabled, cannot carry on any self care, totally confined to bed/chair; 5=dead.			
Units: Subjects			
ECOG=0	5	267	
ECOG=1	0	147	
ECOG=2	0	34	
Missing ECOG Data	0	1	
Time From Diagnosis to First Dose			
Units: years			
median	4.80		
full range (min-max)	1.74 to 18.60	-	

End points

End points reporting groups

Reporting group title	Cohort A: CP-CML R-I

Reporting group description:

CP-CML participants R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort B: CP-CML with T315I Mutation

Reporting group description:

CP-CML participants who had T315I mutation of breakpoint cluster region-Abelson complex (BCR-ABL) were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort C: AP-CML R-I

Reporting group description:

AP-CML R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort D: AP-CML with T315I Mutation

Reporting group description:

AP-CML participants who had T315I mutation of BCR-ABL were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort E: BP-CML/Ph+ ALL R-I

Reporting group description:

BP-CML or Ph+ ALL R-I to dasatinib or nilotinib or Ph+ ALL R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort F: BP-CML or Ph+ ALL with T315I Mutation

Reporting group description:

BP-CML or Ph+ ALL participants who had T315I mutation of BCR-ABL were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Unassigned to Cohorts A-F

Reporting group description:

Participants who were not assigned to any of the cohorts and have no T315I mutation at study entry and were not resistant or intolerant to dasatinib or nilotinib, administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Primary: Percentage of CP-CML Participants with Major Cytogenetic Response (MCyR)

End point title	Percentage of CP-CML Participants with Major Cytogenetic Response (MCyR)[1][2]

End point description:

MCyR is defined as percentage of participants with complete cytogenetic response (CCyR) or partial cytogenetic response (PCyR). Cytogenetic response is the percentage of Philadelphia chromosome positive (Ph+) metaphases in bone marrow (BM). Response is further defined as MCyR: CCyR or PCyR, where CCyR: no Ph+ cells; PCyR: 1 to 35% Ph+ cells. Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. The data for this outcome measure is applicable for Cohorts A and B only.

End point type	Primary

End point timeframe:

Up to 12 months after initiation of study treatment

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only in Cohorts C and D.

[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: This endpoint was analyzed only in Cohorts A and B.

End point values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	64		
Units: percentage of participants				
number (confidence interval 95%)	50.7 (43.6 to 57.8)	70.3 (57.6 to 81.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of AP-CML Participants with Major Hematologic Response (MaHR)

End point title	Percentage of AP-CML Participants with Major Hematologic Response (MaHR)[3][4]

End point description:

MaHR is defined as percentage of participants with complete hematologic response (CHR) or no evidence of leukemia(NEL). Response criteria for CHR is reported as white blood cells(WBC)≤institutional upper limit of normal (ULN), absolute neutrophil count (ANC)≥1000/mm^3, platelets≥100,000/mm^3, no blasts or promyelocytes in peripheral blood,BM blasts ≤5%,<5% myelocytes plus metamyelocytes in peripheral blood,basophils in peripheral blood <5%,no extramedullary involvement;Response criteria for NEL is reported as WBC≤institutional ULN,no blasts or promyelocytes in peripheral blood,BM blasts ≤5%,<5% myelocytes plus metamyelocytes in peripheral blood, basophils in peripheral blood <5%,no extramedullary involvement,at least 1 of the following:(i)20,000/mm^3≤platelets<100,000/mm^3;(ii)500/mm^3≤ANC<1000/mm^3.Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib.The data for this outcome measure is applicable for Cohorts C and D only.

End point type	Primary

End point timeframe:

Up to 6 months after initiation of study treatment

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only in Cohorts C and D.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in Cohorts c and D.

End point values	Cohort C: AP-CML R-I	Cohort D: AP-CML with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65	18		
Units: percentage of participants				
number (confidence interval 95%)	56.9 (44.0 to 69.2)	55.6 (30.8 to 78.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of BP-CML/Ph+ ALL Participants with MaHR

End point title	Percentage of BP-CML/Ph+ ALL Participants with MaHR[5][6]

End point description:

MaHR is defined as percentage of participants with CHR or NEL. Response criteria for CHR is reported as WBC≤institutional upper limit of normal, ANC≥1000/mm^3, platelets ≥100,000/mm^3, no blasts or promyelocytes in peripheral blood, BM blasts ≤5%, <5% myelocytes plus metamyelocytes in peripheral blood, basophils in peripheral blood <5%, no extramedullary involvement; Response criteria for NEL is reported as WBC≤ institutional upper limit of normal, no blasts or promyelocytes in peripheral blood, BM blasts ≤5%, <5% myelocytes plus metamyelocytes in peripheral blood, basophils in peripheral blood <5%, no extramedullary involvement, at least 1 of the following: (i) 20,000/mm^3 ≤platelets<100,000/mm^3; (ii) 500/mm^3≤ANC<1000/mm^3. Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. The data for this outcome measure is applicable for Cohorts E and F only.

End point type	Primary

End point timeframe:

Up to 6 months after initiation of study treatment

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only in Cohorts E and F.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in Cohorts E and F.

End point values	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	46		
Units: percentage of participants				
number (confidence interval 95%)	35.4 (22.2 to 50.5)	32.6 (19.5 to 48.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CP-CML Participants with CHR

End point title	Percentage of CP-CML Participants with CHR[7]

End point description:

Response criteria for CHR is reported as WBC≤institutional upper limit of normal, platelets<450,000/mm^3, no blasts or promyelocytes in peripheral blood, <5% myelocytes plus metamyelocytes in peripheral blood, basophils in peripheral blood <5%, no extramedullary involvement (including no hepatomegaly or splenomegaly). Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. The data for this outcome measure is applicable for Cohorts A and B only.

End point type	Secondary

End point timeframe:

Every 3 cycles up to 39 cycles, followed by every subsequent sixth cycle (Up to approximately 48 months after first dose)

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: This endpoint was analyzed only in Cohorts A and B.

End point values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	64		
Units: percentage of participants				
number (confidence interval 95%)	94.6 (90.5 to 97.3)	92.2 (82.7 to 97.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CP-CML Participants with Confirmed MCyR

End point title	Percentage of CP-CML Participants with Confirmed MCyR[8]

End point description:

Confirmed MCyR is defined as 2 assessments of CCyR or PCyR at least 28 days apart. For CP participants entering the trial in PCyR, confirmed MCyR is defined as 2 assessments of CCyR at least 28 days apart. Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. The data for this outcome measure is applicable for Cohorts A and B only.

End point type	Secondary

End point timeframe:

Every 3 cycles up to 39 cycles, followed by every subsequent sixth cycle (Up to approximately 48 months after first dose)

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: This endpoint was analyzed only in Cohorts A and B.

End point values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	64		
Units: percentage of participants				
number (confidence interval 95%)	40.9 (34.1 to 48.0)	62.5 (49.5 to 74.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CP-CML Participants with Major Molecular Response (MMR)

End point title	Percentage of CP-CML Participants with Major Molecular Response (MMR)[9]

End point description:

MMR is defined as a ratio of reverse transcribed transcript of BCR-ABL to ABL ≤0.1% on the international scale (equivalent to a 3-log reduction in transcript). Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. The data for this outcome measure is applicable for Cohorts A and B only.

End point type	Secondary

End point timeframe:

Every 3 cycles up to 39 cycles, followed by every subsequent sixth cycle (Up to approximately 48 months after first dose)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in Cohorts A and B.

End point values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	203	64		
Units: percentage of participants				
number (confidence interval 95%)	35.0 (28.4 to 42.0)	57.8 (44.8 to 70.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of AP-CML or BP-CML/Ph+ ALL Participants with MCyR

End point title	Percentage of AP-CML or BP-CML/Ph+ ALL Participants with MCyR[10]

End point description:

MCyR is defined as percentage of participants with CCyR or PCyR. Cytogenetic response is the percentage of Ph+ metaphases in BM. Response is further defined as MCyR: CCyR or PCyR, where CCyR: no Ph+ cells; PCyR: 1 to 35% Ph+ cells. Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. The data for this outcome measure is applicable for Cohorts C to F only.

End point type	Secondary

End point timeframe:

Every 2 cycles up to 26 cycles, followed by every 3 cycles from cycles 27 through 39, and then every

subsequent sixth cycle (Up to approximately 48 months after first dose)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in Cohorts C, D, E and F.

End point values	Cohort C: AP-CML R-I	Cohort D: AP-CML with T315I Mutation	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	18	48	46
Units: percentage of participants				
number (confidence interval 95%)	33.8 (22.6 to 46.6)	55.6 (30.8 to 78.5)	27.1 (15.3 to 41.8)	34.8 (21.4 to 50.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of AP-CML or BP-CML/Ph+ ALL Participants with Confirmed MCyR

End point title	Percentage of AP-CML or BP-CML/Ph+ ALL Participants with Confirmed MCyR[11]

End point description:

Confirmed MCyR is defined as 2 assessments of CCyR or PCyR at least 28 days apart. Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. The data for this outcome measure is applicable for Cohorts C to F only.

End point type	Secondary

End point timeframe:

Every 2 cycles up to 26 cycles, followed by every 3 cycles from cycles 27 through 39, and then every subsequent sixth cycle (Up to approximately 48 months after first dose)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in Cohorts C, D, E and F.

End point values	Cohort C: AP-CML R-I	Cohort D: AP-CML with T315I Mutation	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	18	48	46
Units: percentage of participants				
number (confidence interval 95%)	24.6 (14.8 to 36.9)	38.9 (17.3 to 64.3)	20.8 (10.5 to 35.0)	15.2 (6.3 to 28.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of AP-CML or BP-CML/Ph+ ALL Participants with MMR

End point title	Percentage of AP-CML or BP-CML/Ph+ ALL Participants with MMR[12]

End point description:

MMR is defined as a ratio of reverse transcribed transcript of BCR-ABL to ABL ≤0.1% on the international scale (equivalent to a 3-log reduction in transcript). Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. The data for this outcome measure is applicable for Cohorts C to F only.

End point type	Secondary

End point timeframe:

Every 2 cycles up to 26 cycles, followed by every 3 cycles from cycles 27 through 39, and then every subsequent sixth cycle (Up to approximately 48 months after first dose)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in Cohorts E and F.

End point values	Cohort C: AP-CML R-I	Cohort D: AP-CML with T315I Mutation	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	18	48	46
Units: percentage of participants				
number (confidence interval 95%)	18.5 (9.9 to 30.0)	33.3 (13.3 to 59.0)	18.8 (8.9 to 32.6)	4.3 (0.5 to 14.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response

End point title	Time to Response[13]

End point description:

Time to response is defined as the interval from the first dose of study treatment until the criteria for response are first met, censored at the last assessment of response. Median time to response was estimated using the Kaplan-Meier method. Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. Median time to response was reported for responders only. Participants who did not achieve the specified response were censored at the last response assessment. Number analysed: participants with data available at given time-point.

End point type	Secondary

End point timeframe:

Up to approximately 48 months after first dose

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in all Cohorts except the unassigned cohorts.

End point values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation	Cohort C: AP-CML R-I	Cohort D: AP-CML with T315I Mutation
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	64	65	18
Units: days				
median (full range (min-max))				
Hematologic Response (n= 192, 59, 37, 10, 17, 15)	13.0 (1 to 417)	10.0 (4 to 1008)	21.0 (12 to 112)	20.5 (14 to 176)
Cytogenetic Response (n= 103, 45, 22, 10, 13, 16)	85.0 (56 to 343)	84.0 (49 to 333)	113.5 (26 to 280)	83.0 (25 to 295)
Molecular Response (n= 71, 37, 12, 6, 9, 2)	173.0 (55 to 1686)	167.0 (81 to 756)	340.5 (55 to 1364)	335.5 (107 to 925)

End point values	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	46		
Units: days				
median (full range (min-max))				
Hematologic Response (n= 192, 59, 37, 10, 17, 15)	28.0 (14 to 168)	24.0 (11 to 57)		
Cytogenetic Response (n= 103, 45, 22, 10, 13, 16)	28.0 (28 to 168)	56.0 (27 to 112)		
Molecular Response (n= 71, 37, 12, 6, 9, 2)	56.0 (54 to 113)	63.0 (59 to 67)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response[14]

End point description:

Duration of Response is defined as the interval between the first assessment at which the criteria for response are met until the criteria for progression are met, censored at the last date at which the criteria for response are met. Duration of response was estimated by the Kaplan-Meier method as the probability of remaining in response. Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. Number analysed is number of participants with data available for analysis at given time-point. 9999 indicates duration of response was not reached for Cohorts A and B due to fewer number of participants with events. 99999 indicates duration of response was not reached due to fewer number of participants with events.

End point type	Secondary

End point timeframe:

Up to approximately 48 months after first dose

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in all Cohorts except the unassigned cohorts.

End point values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation	Cohort C: AP-CML R-I	Cohort D: AP-CML with T315I Mutation
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	64	65	18
Units: days				
median (full range (min-max))				
Hematologic Response (n= 192, 59, 37, 10, 17, 15)	9999 (9999 to 9999)	9999 (9999 to 9999)	360.0 (35 to 2079)	732.0 (42 to 1334)
Cytogenetic Response (n= 103, 45, 22, 10, 13, 16)	9999 (9999 to 9999)	9999 (9999 to 9999)	99999 (99999 to 99999)	728.0 (28 to 1569)
Molecular Response (n= 71, 37, 12, 6, 9, 2)	9999 (9999 to 9999)	9999 (9999 to 9999)	560.0 (1 to 1666)	222.0 (1 to 783)

End point values	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	46		
Units: days				
median (full range (min-max))				
Hematologic Response (n= 192, 59, 37, 10, 17, 15)	196.0 (54 to 1811)	108.0 (54 to 1038)		
Cytogenetic Response (n= 103, 45, 22, 10, 13, 16)	99999 (99999 to 99999)	63.0 (1 to 673)		
Molecular Response (n= 71, 37, 12, 6, 9, 2)	99999 (99999 to 99999)	98.0 (1 to 98)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS)

End point title	Progression-free Survival (PFS)[15]

End point description:

PFS is interval from first dose of study drug until criteria for progression or death are met,censored at last response assessment.Progression from CP reported as death,development of AP or BP,loss of CHR (in absence of cytogenetic response),confirmed by development in complete blood counts(CBCs) >=4weeks apart,loss of MCyR,increasing WBC in participant without CHR defined by doubling of WBC to >20K on 2 occasions >=4weeks apart;Progression from AP reported as death,development of confirmed BP,loss of previous major or minor hematologic response over a 2-week period,no decrease from baseline levels in percentage blasts in peripheral blood or BM on all assessments over a 4-week period;Progression from BP or Ph+ ALL reported as death, increasing blasts in peripheral blood or BM over a 4 week period.Treated population:participants assigned to Cohorts A to F who received >=1 dose of ponatinib.999999:PFS was not reached for Cohorts A and B due to fewer number of participants with events.

End point type	Secondary

End point timeframe:

Every 12 weeks ± 2 weeks from last dose of study drug or the investigator/participant decision to discontinue treatment, whichever occurred later (Up to approximately 96 months after last dose)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in all Cohorts except the unassigned cohorts.

End point values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation	Cohort C: AP-CML R-I	Cohort D: AP-CML with T315I Mutation
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	64	65	18
Units: days				
median (confidence interval 95%)	999999 (1285.0 to 999999)	1809.0 (1028.0 to 999999)	432.0 (335.0 to 714.0)	959.0 (186.0 to 1847.0)

End point values	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	46		
Units: days				
median (confidence interval 95%)	111.0 (55.0 to 169.0)	83.0 (55.0 to 150.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)[16]

End point description:

OS is defined as the interval from the first dose of study treatment until death, censored at the last date at which participant was known to be alive. Treated population included all participants assigned to Cohorts A to F who received at least 1 dose of ponatinib. 9999999 indicates median OS has not been reached for Cohort A and B due to fewer number of participants with events. 99999999 indicates uper limit of 95% confidence interval was not estimable due to fewer number of participants with events.

End point type	Secondary

End point timeframe:

From the first dose of study treatment until death (Up to 96 months post last dose)

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only in all Cohorts except the unassigned cohorts.

End point values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation	Cohort C: AP-CML R-I	Cohort D: AP-CML with T315I Mutation
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	64	65	18
Units: days				
median (confidence interval 95%)	9999999 (9999999 to 9999999)	9999999 (9999999 to 9999999)	1689.0 (969.0 to 99999999)	1847.0 (281.0 to 2143.0)

End point values	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	46		
Units: days				
median (confidence interval 95%)	209.0 (119.0 to 379.0)	200.0 (150.0 to 279.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment-Emergent Adverse Event (TEAE) and Serious AE (SAE)

End point title	Number of Participants with Treatment-Emergent Adverse Event (TEAE) and Serious AE (SAE)

End point description:

AE is any untoward medical occurrence in a participant administered medicinal investigational drug.Untoward medical occurrence does not necessarily have to have causal relationship with treatment.SAE is any untoward medical occurrence that results in death;is life-threatening;requires inpatient hospitalization or prolongation of present hospitalization;results in persistent or significant disability/incapacity;is congenital anomaly/birth defect or is medically important event that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the participant or may require intervention to prevent one of other outcomes listed in definition above,or involves suspected transmission via medicinal product of infectious agent.TEAE:an AE that occurs after administration of first dose and through 30 days after last dose of study drug or until start of subsequent antineoplastic therapy.Safety population:participants who received >=1 dose of ponatinib.

End point type	Secondary

End point timeframe:

From first dose up to 30 days after last dose of the study drug (Up to approximately 49 months)

End point values	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation	Cohort C: AP-CML R-I	Cohort D: AP-CML with T315I Mutation
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	64	65	18
Units: participants				
TEAE	203	64	65	18
SAE	132	39	44	13

End point values	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation	Unassigned to Cohorts A-F	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	46	5	
Units: participants				
TEAE	48	46	5	
SAE	41	37	3	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs and Other AEs: From first dose up to 30 days after last dose of the study drug (Up to approximately 49 months); All-Cause Mortality: Up to approximately 8 years

Adverse event reporting additional description:

At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Cohort A: CP-CML R-I

Reporting group description:

CP-CML participants R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort B: CP-CML with T315I Mutation

Reporting group description:

CP-CML participants who had T315I mutation of breakpoint cluster region-Abelson complex (BCR-ABL) were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort C: AP-CML R-I

Reporting group description:

AP-CML R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort D: AP-CML with T315I Mutation

Reporting group description:

AP-CML participants who had T315I mutation of BCR-ABL were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort E: BP-CML/Ph+ ALL R-I

Reporting group description:

BP-CML or Ph+ ALL R-I to dasatinib or nilotinib or Ph+ ALL R-I to dasatinib or nilotinib were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Cohort F: BP-CML or Ph+ ALL with T315I Mutation

Reporting group description:

BP-CML or Ph+ ALL participants who had T315I mutation of BCR-ABL were administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Reporting group title	Unassigned AP/CP-CML

Reporting group description:

Participants who were not assigned to any of the cohorts and have no T315I mutation at study entry and were not R-I to dasatinib or nilotinib, administered ponatinib 45 mg, tablet, orally, once daily until disease progression or development of intolerance or if they met one or more of the protocol defined criteria for discontinuation (Up to approximately 48 months).

Serious adverse events	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation	Cohort C: AP-CML R-I
Total subjects affected by serious adverse events			
subjects affected / exposed	132 / 203 (65.02%)	39 / 64 (60.94%)	44 / 65 (67.69%)
number of deaths (all causes)	11	5	5
number of deaths resulting from adverse events	2	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm progression			
subjects affected / exposed	6 / 203 (2.96%)	2 / 64 (3.13%)	7 / 65 (10.77%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 2
Myelodysplastic syndrome			
subjects affected / exposed	3 / 203 (1.48%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant pleural effusion			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blast crisis in myelogenous leukaemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma of skin			

subjects affected / exposed	3 / 203 (1.48%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chloroma			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Colon cancer			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin squamous cell carcinoma metastatic			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Large cell lung cancer recurrent			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Non-hodgkin's lymphoma			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Squamous cell carcinoma			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval cancer			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system leukaemia			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	11 / 203 (5.42%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	8 / 13	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Deep vein thrombosis			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hot flush			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Peripheral ischaemia			
subjects affected / exposed	3 / 203 (1.48%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism venous			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	10 / 203 (4.93%)	4 / 64 (6.25%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	8 / 10	4 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	4 / 203 (1.97%)	3 / 64 (4.69%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	3 / 6	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			

subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	3 / 6	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dry gangrene			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic arteriosclerosis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Temporal arteritis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac artery occlusion			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism arterial			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	5 / 203 (2.46%)	3 / 64 (4.69%)	5 / 65 (7.69%)
occurrences causally related to treatment / all	1 / 5	2 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 4	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 203 (0.00%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site pain			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent occlusion			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Fatigue			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Graft versus host disease in skin			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactoid reaction			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Immobile			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Prostatic obstruction			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 203 (0.99%)	3 / 64 (4.69%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	2 / 3	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	3 / 203 (1.48%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory failure			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
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 hypertension			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	3 / 203 (1.48%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Mental status changes			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Lipase increased			
subjects affected / exposed	4 / 203 (1.97%)	3 / 64 (4.69%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	4 / 4	3 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	2 / 6	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	3 / 203 (1.48%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	2 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ejection fraction decreased			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine analysis abnormal			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio increased			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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

Blood potassium increased			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Haemoglobin decreased			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
JC polyomavirus test positive			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Injury, poisoning and procedural complications			
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Concussion			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Peripancreatic fluid collection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Procedural vomiting			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subdural haematoma			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis chemical			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery restenosis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column injury			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Wrist fracture			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	11 / 203 (5.42%)	4 / 64 (6.25%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	9 / 21	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	5 / 203 (2.46%)	3 / 64 (4.69%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	4 / 5	2 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coronary artery disease			
subjects affected / exposed	4 / 203 (1.97%)	6 / 64 (9.38%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	2 / 4	5 / 7	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 5	1 / 2	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Angina pectoris			

subjects affected / exposed	10 / 203 (4.93%)	4 / 64 (6.25%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	8 / 13	3 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Coronary artery stenosis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	3 / 3	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	3 / 203 (1.48%)	3 / 64 (4.69%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	3 / 3	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			

subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Coronary artery occlusion			

subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia supraventricular			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriospasm coronary			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Bradycardia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Discomfort			

subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Cardio-respiratory arrest			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Dressler's syndrome			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Sinus node dysfunction			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Cardiac failure chronic			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle branch block right			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
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	3 / 203 (1.48%)	4 / 64 (6.25%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	1 / 3	3 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	5 / 203 (2.46%)	4 / 64 (6.25%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	2 / 7	1 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Headache			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	2 / 203 (0.99%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery stenosis			
subjects affected / exposed	0 / 203 (0.00%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	5 / 203 (2.46%)	3 / 64 (4.69%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	4 / 5	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebral infarction			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
IVth nerve paralysis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Spinal cord compression			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	2 / 3	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paralysis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IIIrd nerve paralysis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			

subjects affected / exposed	5 / 203 (2.46%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	2 / 5	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Encephalopathy			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Intracranial aneurysm			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory impairment			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 203 (3.45%)	0 / 64 (0.00%)	4 / 65 (6.15%)
occurrences causally related to treatment / all	2 / 9	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperviscosity syndrome			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperleukocytosis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	4 / 65 (6.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal vein occlusion			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystoid macular oedema			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal artery occlusion			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Retinal vein thrombosis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Ulcerative keratitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Macular fibrosis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Pancreatitis			
subjects affected / exposed	10 / 203 (4.93%)	4 / 64 (6.25%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	9 / 10	4 / 5	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	7 / 203 (3.45%)	1 / 64 (1.56%)	4 / 65 (6.15%)
occurrences causally related to treatment / all	6 / 9	1 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	3 / 3	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute abdomen			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis Noninfective			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ischaemic			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula of small intestine			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric arterial occlusion			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			

subjects affected / exposed	5 / 203 (2.46%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 10	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			

subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Biliary dilatation			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder obstruction			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Erythema multiforme			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkeratosis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Skin ulcer			

subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin swelling			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucocutaneous haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash erythematous			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Renal and urinary disorders			
Renal failure			

subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	2 / 203 (0.99%)	2 / 64 (3.13%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
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 pain			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
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 column stenosis			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	10 / 203 (4.93%)	5 / 64 (7.81%)	8 / 65 (12.31%)
occurrences causally related to treatment / all	2 / 13	0 / 8	1 / 9
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	2 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	5 / 203 (2.46%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			

subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Bronchitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes oesophagitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Wound infection			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Bacteraemia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cellulitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
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	3 / 203 (1.48%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Splenic abscess			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site cellulitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Haematoma infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
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 respiratory syncytial viral			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis viral			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Clostridium difficile infection			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Genital infection bacterial			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Viral infection			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Wound infection staphylococcal			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (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
Gangrene			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious colitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
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 influenzal			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	2 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	4 / 203 (1.97%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (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
Hyperkalaemia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort D: AP-CML with T315I Mutation	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 18 (72.22%)	41 / 48 (85.42%)	37 / 46 (80.43%)
number of deaths (all causes)	5	20	14
number of deaths resulting from adverse events	1	2	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm progression			
subjects affected / exposed	4 / 18 (22.22%)	14 / 48 (29.17%)	8 / 46 (17.39%)
occurrences causally related to treatment / all	0 / 4	0 / 14	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 10	0 / 5
Myelodysplastic syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant pleural effusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blast crisis in myelogenous leukaemia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chloroma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin squamous cell carcinoma metastatic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large cell lung cancer recurrent			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-hodgkin's lymphoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval cancer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system leukaemia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute lymphocytic leukaemia recurrent			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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			
Hypertension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hot flush			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Extremity necrosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism venous			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			

subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	1 / 2	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dry gangrene			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic arteriosclerosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal arteritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac artery occlusion			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism arterial			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Intermittent claudication			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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			
Pyrexia			
subjects affected / exposed	2 / 18 (11.11%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 2	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			

subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Impaired healing			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 stent occlusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease in skin			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Anaphylactic reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactoid reaction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Immobile			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast			

disorders			
Prostatic obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epistaxis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Pleuritic pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Pneumonitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Product issues			
Device dislocation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Lipase increased			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neutrophil count decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine analysis abnormal			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio			

increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 potassium increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JC polyomavirus test positive			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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			
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripancreatic fluid collection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Procedural vomiting			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonitis chemical			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery restenosis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 column injury			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coronary artery disease			

subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	2 / 18 (11.11%)	2 / 48 (4.17%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Coronary artery stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure			
subjects affected / exposed	1 / 18 (5.56%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Cardiac tamponade			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Pericarditis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Arrhythmia supraventricular			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriospasm coronary			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 Discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dressler's syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle branch block right			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Left ventricular failure			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Nervous system disorders			
Cerebrovascular accident			

subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (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
Headache			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebral infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IVth nerve paralysis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dizziness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Brain oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Dementia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (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
Facial Paralysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IIIrd nerve paralysis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory impairment			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	1 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	1 / 18 (5.56%)	5 / 48 (10.42%)	5 / 46 (10.87%)
occurrences causally related to treatment / all	1 / 1	1 / 6	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	1 / 1	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperviscosity syndrome			

subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hyperleukocytosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystoid macular oedema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal artery occlusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein thrombosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (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
Ulcerative keratitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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			
Pancreatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	1 / 18 (5.56%)	4 / 48 (8.33%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 1	1 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	1 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	2 / 48 (4.17%)	0 / 46 (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
Colitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Oesophagitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Acute abdomen			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Gastritis haemorrhagic			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Stomatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis Noninfective			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 Ischaemic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula of small intestine			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric arterial occlusion			

subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 acute			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	0 / 46 (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			
Bile duct stone			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dilatation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder obstruction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkeratosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin swelling			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucocutaneous haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash erythematous			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Haematuria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 osteoarthritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bone pain			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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			
Pneumonia			
subjects affected / exposed	1 / 18 (5.56%)	4 / 48 (8.33%)	5 / 46 (10.87%)
occurrences causally related to treatment / all	0 / 1	0 / 6	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Upper respiratory tract infection			

subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Urinary tract infection			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Diverticulitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes oesophagitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 syncytial virus infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cellulitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	0 / 46 (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
Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Pharyngitis streptococcal			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Splenic abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site cellulitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Gastroenteritis			

subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	0 / 46 (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
Haematoma infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Post procedural infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis viral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 infective			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital infection bacterial			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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 mycoplasmal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic infection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection staphylococcal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (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
Oesophageal candidiasis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious colitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Postoperative wound infection			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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			
Hyponatraemia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Fluid overload			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (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
Fluid retention			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
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	Unassigned AP/CP-CML		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm progression			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelodysplastic syndrome			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Malignant pleural effusion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Basal cell carcinoma				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blast crisis in myelogenous leukaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of skin				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chloroma				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon cancer				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin squamous cell carcinoma metastatic				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large cell lung cancer recurrent				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-hodgkin's lymphoma				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vulval cancer				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Central nervous system leukaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute lymphocytic leukaemia recurrent				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma metastatic				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bowen's disease				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				

Hypertension				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hot flush				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extremity necrosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism venous				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis superficial				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral arterial occlusive disease				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery stenosis				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral artery occlusion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral vascular disorder				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dry gangrene				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic arteriosclerosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Temporal arteritis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Varicose vein				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vasculitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coeliac artery occlusion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism arterial				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intermittent claudication				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Pyrexia				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthenia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chest pain				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chills				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic inflammatory response syndrome				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Implant site pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impaired healing				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gait disturbance				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular stent occlusion				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Hypersensitivity				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Graft versus host disease in skin				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic reaction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactoid reaction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug hypersensitivity				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Social circumstances				

Immobile				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Prostatic obstruction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostatitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic ovarian cyst				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Dyspnoea				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Dyspnoea exertional				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleuritic pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary hypertension				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Confusional state				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Product issues				
Device dislocation				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Lipase increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Platelet count decreased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Alanine aminotransferase increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutrophil count decreased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood alkaline phosphatase increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ejection fraction decreased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood bilirubin increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspartate aminotransferase increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urine analysis abnormal				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
International normalised ratio increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood potassium increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoglobin decreased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
JC polyomavirus test positive				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Subarachnoid haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripancreatic fluid collection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural vomiting				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural haematoma				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic intracranial haemorrhage				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis chemical				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery restenosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal column injury				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound dehiscence				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrist fracture				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Atrial fibrillation				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute myocardial infarction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial tachycardia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus tachycardia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute coronary syndrome				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiopulmonary failure				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac tamponade				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiogenic shock				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericarditis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Right ventricular failure				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery occlusion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute left ventricular failure				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina unstable				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve stenosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arrhythmia supraventricular				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis coronary artery				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriospasm coronary				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Discomfort				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure acute				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congestive cardiomyopathy				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dressler's syndrome				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic cardiomyopathy				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Left ventricular dysfunction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mitral valve incompetence				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus node dysfunction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular tachycardia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure chronic				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bundle branch block right				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Left ventricular failure				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebrovascular accident				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ataxia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral artery stenosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic cerebral infarction				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic transformation stroke				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
IVth nerve paralysis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal cord compression				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebellar infarction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral ischaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Migraine				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Somnolence				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain oedema				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Status epilepticus				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dementia				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial Paralysis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
IIIrd nerve paralysis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuropathy peripheral				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carotid artery stenosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular disorder				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intracranial aneurysm				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lacunar infarction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Memory impairment				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sciatica				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carotid artery occlusion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic infarction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperviscosity syndrome				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperleukocytosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphadenopathy				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
Vertigo positional				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vertigo				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Retinal vein occlusion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cataract				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystoid macular oedema				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinal artery occlusion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinal vein thrombosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ulcerative keratitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vision blurred				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Macular fibrosis				

subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Pancreatitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hiatus hernia			

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal haemorrhage				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Retroperitoneal haematoma				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				

subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Abdominal distension				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute abdomen				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis haemorrhagic				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis Noninfective				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis Ischaemic				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Faecaloma				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fistula of small intestine				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritoneal haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mesenteric arterial occlusion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Bile duct stone				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis acute				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Portal vein thrombosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-alcoholic steatohepatitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venoocclusive liver disease				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary dilatation				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gallbladder obstruction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Angioedema				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythema				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythema multiforme				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperkeratosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin ulcer				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute febrile neutrophilic dermatosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dermatitis exfoliative generalised				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin swelling				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic foot				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mucocutaneous haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash erythematous				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash maculo-papular				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Renal failure				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute kidney injury				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal artery stenosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				

subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dysuria				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Thyroid mass				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Spinal osteoarthritis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal column stenosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Pneumonia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes oesophagitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cellulitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised infection				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis streptococcal				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia fungal				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic abscess				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella sepsis				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Catheter site cellulitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematoma infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis externa				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal sepsis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis bacterial				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis viral				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis infective				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Genital infection bacterial				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media chronic				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia mycoplasmal				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection staphylococcal				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia staphylococcal				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gangrene				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis norovirus				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Kidney infection				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal candidiasis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atypical pneumonia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infectious colitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia influenzal				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hyponatraemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrolyte imbalance				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour lysis syndrome				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				

subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fluid overload				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fluid retention				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperuricaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Cohort A: CP-CML R-I	Cohort B: CP-CML with T315I Mutation	Cohort C: AP-CML R-I
Total subjects affected by non-serious adverse events			
subjects affected / exposed	203 / 203 (100.00%)	64 / 64 (100.00%)	65 / 65 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	8 / 203 (3.94%)	2 / 64 (3.13%)	4 / 65 (6.15%)
occurrences (all)	11	2	4
Haemorrhage			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	12 / 203 (5.91%)	1 / 64 (1.56%)	4 / 65 (6.15%)
occurrences (all)	13	1	4
Hypertension			
subjects affected / exposed	68 / 203 (33.50%)	21 / 64 (32.81%)	13 / 65 (20.00%)
occurrences (all)	92	25	13
Hypotension			
subjects affected / exposed	6 / 203 (2.96%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	6	0	1
Peripheral ischaemia			
subjects affected / exposed	0 / 203 (0.00%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Peripheral venous disease			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	40 / 203 (19.70%)	8 / 64 (12.50%)	5 / 65 (7.69%)
occurrences (all)	50	10	5
Chest pain			
subjects affected / exposed	13 / 203 (6.40%)	4 / 64 (6.25%)	1 / 65 (1.54%)
occurrences (all)	17	4	1
Chills			
subjects affected / exposed	16 / 203 (7.88%)	4 / 64 (6.25%)	6 / 65 (9.23%)
occurrences (all)	20	4	7
Fatigue			
subjects affected / exposed	60 / 203 (29.56%)	21 / 64 (32.81%)	22 / 65 (33.85%)
occurrences (all)	77	29	28
Feeling hot			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			

subjects affected / exposed	1 / 203 (0.49%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences (all)	1	2	0
Hernia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	10 / 203 (4.93%)	3 / 64 (4.69%)	4 / 65 (6.15%)
occurrences (all)	13	5	6
Localised oedema			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Non-cardiac chest pain			
subjects affected / exposed	13 / 203 (6.40%)	6 / 64 (9.38%)	3 / 65 (4.62%)
occurrences (all)	13	6	3
Oedema peripheral			
subjects affected / exposed	36 / 203 (17.73%)	8 / 64 (12.50%)	9 / 65 (13.85%)
occurrences (all)	48	15	9
Pain			
subjects affected / exposed	19 / 203 (9.36%)	7 / 64 (10.94%)	8 / 65 (12.31%)
occurrences (all)	23	10	8
Performance status decreased			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	5 / 203 (2.46%)	4 / 64 (6.25%)	5 / 65 (7.69%)
occurrences (all)	6	5	5
Pyrexia			
subjects affected / exposed	52 / 203 (25.62%)	13 / 64 (20.31%)	20 / 65 (30.77%)
occurrences (all)	77	14	31
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Activities of daily living impaired			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast mass			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	9 / 203 (4.43%)	6 / 64 (9.38%)	4 / 65 (6.15%)
occurrences (all)	9	6	4
Testicular pain			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Catarrh			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	36 / 203 (17.73%)	11 / 64 (17.19%)	15 / 65 (23.08%)
occurrences (all)	47	15	21
Dysphonia			
subjects affected / exposed	14 / 203 (6.90%)	5 / 64 (7.81%)	1 / 65 (1.54%)
occurrences (all)	17	5	1
Dyspnoea			
subjects affected / exposed	30 / 203 (14.78%)	14 / 64 (21.88%)	12 / 65 (18.46%)
occurrences (all)	37	16	13
Epistaxis			
subjects affected / exposed	16 / 203 (7.88%)	3 / 64 (4.69%)	6 / 65 (9.23%)
occurrences (all)	22	3	7
Nasal congestion			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	2	1	2
Oropharyngeal pain			

subjects affected / exposed	12 / 203 (5.91%)	6 / 64 (9.38%)	4 / 65 (6.15%)
occurrences (all)	15	6	4
Pharyngeal erythema			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	9	9
Pleural effusion			
subjects affected / exposed	10 / 203 (4.93%)	2 / 64 (3.13%)	7 / 65 (10.77%)
occurrences (all)	10	2	8
Productive cough			
subjects affected / exposed	6 / 203 (2.96%)	2 / 64 (3.13%)	2 / 65 (3.08%)
occurrences (all)	7	4	2
Sleep apnoea syndrome			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	10 / 203 (4.93%)	3 / 64 (4.69%)	11 / 65 (16.92%)
occurrences (all)	10	3	14
Confusional state			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	5	1	1
Depression			
subjects affected / exposed	13 / 203 (6.40%)	2 / 64 (3.13%)	5 / 65 (7.69%)
occurrences (all)	14	2	5
Hallucination			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Hallucination, visual			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	25 / 203 (12.32%)	5 / 64 (7.81%)	10 / 65 (15.38%)
occurrences (all)	27	5	10
Libido decreased			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	39 / 203 (19.21%)	12 / 64 (18.75%)	15 / 65 (23.08%)
occurrences (all)	63	27	21
Amylase increased			
subjects affected / exposed	19 / 203 (9.36%)	2 / 64 (3.13%)	6 / 65 (9.23%)
occurrences (all)	24	2	12
Aspartate aminotransferase increased			
subjects affected / exposed	31 / 203 (15.27%)	11 / 64 (17.19%)	11 / 65 (16.92%)
occurrences (all)	46	20	12
Blood alkaline phosphatase increased			
subjects affected / exposed	20 / 203 (9.85%)	5 / 64 (7.81%)	9 / 65 (13.85%)
occurrences (all)	24	5	9
Blood bilirubin increased			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	4 / 65 (6.15%)
occurrences (all)	2	1	7
Blood cholesterol increased			
subjects affected / exposed	9 / 203 (4.43%)	3 / 64 (4.69%)	1 / 65 (1.54%)
occurrences (all)	11	3	1
Blood creatinine increased			
subjects affected / exposed	8 / 203 (3.94%)	4 / 64 (6.25%)	5 / 65 (7.69%)
occurrences (all)	8	6	8
Blood glucose increased			
subjects affected / exposed	1 / 203 (0.49%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences (all)	1	2	0
Blood phosphorus decreased			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	4	1	0
Blood triglycerides increased			
subjects affected / exposed	6 / 203 (2.96%)	2 / 64 (3.13%)	1 / 65 (1.54%)
occurrences (all)	9	2	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	16 / 203 (7.88%)	5 / 64 (7.81%)	5 / 65 (7.69%)
occurrences (all)	23	5	6
Haemoglobin decreased			

subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	2	1	0
Lipase increased			
subjects affected / exposed	56 / 203 (27.59%)	15 / 64 (23.44%)	10 / 65 (15.38%)
occurrences (all)	79	21	29
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	8 / 203 (3.94%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences (all)	9	2	0
Platelet count decreased			
subjects affected / exposed	15 / 203 (7.39%)	3 / 64 (4.69%)	6 / 65 (9.23%)
occurrences (all)	61	3	9
Platelet count increased			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	3	1	1
Weight decreased			
subjects affected / exposed	23 / 203 (11.33%)	5 / 64 (7.81%)	7 / 65 (10.77%)
occurrences (all)	25	6	8
White blood cell count decreased			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	6	1	2
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	9 / 203 (4.43%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	10	1	4
Hand fracture			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Head injury			

subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Laceration			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	3	1	2
Ligament sprain			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	4	1	1
Procedural pain			
subjects affected / exposed	5 / 203 (2.46%)	2 / 64 (3.13%)	2 / 65 (3.08%)
occurrences (all)	5	2	2
Skin injury			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Subcutaneous haematoma			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Transfusion reaction			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Transfusion related complication			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	9 / 203 (4.43%)	4 / 64 (6.25%)	3 / 65 (4.62%)
occurrences (all)	13	5	3
Atrial fibrillation			
subjects affected / exposed	10 / 203 (4.93%)	3 / 64 (4.69%)	1 / 65 (1.54%)
occurrences (all)	15	4	1
Cardiac failure			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	1	2	1

Cardiomyopathy			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	6 / 203 (2.96%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	7	1	2
Pericardial effusion			
subjects affected / exposed	5 / 203 (2.46%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	5	1	2
Tachycardia			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	3	1	2
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Ataxia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Burning sensation			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	3	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	34 / 203 (16.75%)	12 / 64 (18.75%)	7 / 65 (10.77%)
occurrences (all)	37	13	7
Dysgeusia			
subjects affected / exposed	3 / 203 (1.48%)	6 / 64 (9.38%)	0 / 65 (0.00%)
occurrences (all)	3	6	0
Facial paralysis			
subjects affected / exposed	3 / 203 (1.48%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	4	0	2
Headache			

subjects affected / exposed	87 / 203 (42.86%)	27 / 64 (42.19%)	18 / 65 (27.69%)
occurrences (all)	136	37	26
Hypoaesthesia			
subjects affected / exposed	11 / 203 (5.42%)	2 / 64 (3.13%)	1 / 65 (1.54%)
occurrences (all)	13	2	1
Migraine			
subjects affected / exposed	6 / 203 (2.96%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	6	0	1
Neuropathy peripheral			
subjects affected / exposed	15 / 203 (7.39%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	16	1	2
Paraesthesia			
subjects affected / exposed	15 / 203 (7.39%)	5 / 64 (7.81%)	1 / 65 (1.54%)
occurrences (all)	18	6	1
Radiculopathy			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	11 / 203 (5.42%)	0 / 64 (0.00%)	4 / 65 (6.15%)
occurrences (all)	12	0	4
Somnolence			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Vith nerve disorder			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	39 / 203 (19.21%)	7 / 64 (10.94%)	20 / 65 (30.77%)
occurrences (all)	48	7	41
Febrile neutropenia			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	1	1	2
Hypochromasia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0

Leukopenia			
subjects affected / exposed	7 / 203 (3.45%)	0 / 64 (0.00%)	5 / 65 (7.69%)
occurrences (all)	7	0	6
Lymphadenopathy			
subjects affected / exposed	6 / 203 (2.96%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences (all)	9	0	2
Neutropenia			
subjects affected / exposed	42 / 203 (20.69%)	6 / 64 (9.38%)	24 / 65 (36.92%)
occurrences (all)	133	7	54
Thrombocytopenia			
subjects affected / exposed	90 / 203 (44.33%)	18 / 64 (28.13%)	32 / 65 (49.23%)
occurrences (all)	235	33	97
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	8 / 203 (3.94%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	9	1	1
Vertigo			
subjects affected / exposed	8 / 203 (3.94%)	1 / 64 (1.56%)	3 / 65 (4.62%)
occurrences (all)	8	1	3
Eye disorders			
Blepharitis			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	5	1	2
Cataract			
subjects affected / exposed	7 / 203 (3.45%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	7	1	2
Conjunctival hyperaemia			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	3	0	0
Dry eye			
subjects affected / exposed	16 / 203 (7.88%)	5 / 64 (7.81%)	4 / 65 (6.15%)
occurrences (all)	17	5	5
Eye pain			
subjects affected / exposed	8 / 203 (3.94%)	4 / 64 (6.25%)	2 / 65 (3.08%)
occurrences (all)	9	5	2
Eyelid disorder			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	3	1	0
Vision blurred			
subjects affected / exposed	13 / 203 (6.40%)	6 / 64 (9.38%)	3 / 65 (4.62%)
occurrences (all)	13	6	3
Visual acuity reduced			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Visual impairment			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	3	1	1
Vitreous floaters			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	8 / 203 (3.94%)	3 / 64 (4.69%)	3 / 65 (4.62%)
occurrences (all)	8	4	18
Abdominal distension			
subjects affected / exposed	12 / 203 (5.91%)	7 / 64 (10.94%)	4 / 65 (6.15%)
occurrences (all)	13	8	6
Abdominal pain			
subjects affected / exposed	75 / 203 (36.95%)	21 / 64 (32.81%)	20 / 65 (30.77%)
occurrences (all)	127	30	30
Abdominal pain upper			
subjects affected / exposed	40 / 203 (19.70%)	10 / 64 (15.63%)	11 / 65 (16.92%)
occurrences (all)	58	18	19
Ascites			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	89 / 203 (43.84%)	21 / 64 (32.81%)	16 / 65 (24.62%)
occurrences (all)	131	36	30

Dental necrosis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	43 / 203 (21.18%)	10 / 64 (15.63%)	17 / 65 (26.15%)
occurrences (all)	59	18	29
Dry mouth			
subjects affected / exposed	20 / 203 (9.85%)	6 / 64 (9.38%)	4 / 65 (6.15%)
occurrences (all)	21	6	4
Dyspepsia			
subjects affected / exposed	12 / 203 (5.91%)	6 / 64 (9.38%)	4 / 65 (6.15%)
occurrences (all)	16	6	5
Dysphagia			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	3	1	2
Gastrooesophageal reflux disease			
subjects affected / exposed	10 / 203 (4.93%)	8 / 64 (12.50%)	2 / 65 (3.08%)
occurrences (all)	11	10	2
Gingival bleeding			
subjects affected / exposed	3 / 203 (1.48%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	9	0	1
Haemorrhoids			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	5	1	1
Mouth haemorrhage			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	53 / 203 (26.11%)	24 / 64 (37.50%)	22 / 65 (33.85%)
occurrences (all)	63	33	33
Odynophagia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1

Stomatitis			
subjects affected / exposed	11 / 203 (5.42%)	2 / 64 (3.13%)	4 / 65 (6.15%)
occurrences (all)	11	2	4
Toothache			
subjects affected / exposed	13 / 203 (6.40%)	0 / 64 (0.00%)	3 / 65 (4.62%)
occurrences (all)	14	0	4
Vomiting			
subjects affected / exposed	38 / 203 (18.72%)	12 / 64 (18.75%)	17 / 65 (26.15%)
occurrences (all)	53	20	22
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	3	1	2
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	19 / 203 (9.36%)	4 / 64 (6.25%)	5 / 65 (7.69%)
occurrences (all)	20	4	5
Dry skin			
subjects affected / exposed	84 / 203 (41.38%)	28 / 64 (43.75%)	21 / 65 (32.31%)
occurrences (all)	107	38	27
Ecchymosis			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	4 / 65 (6.15%)
occurrences (all)	2	1	5
Erythema			
subjects affected / exposed	22 / 203 (10.84%)	6 / 64 (9.38%)	6 / 65 (9.23%)
occurrences (all)	32	6	7
Exfoliative rash			
subjects affected / exposed	7 / 203 (3.45%)	2 / 64 (3.13%)	4 / 65 (6.15%)
occurrences (all)	8	2	4
Generalised erythema			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	17 / 203 (8.37%)	7 / 64 (10.94%)	4 / 65 (6.15%)
occurrences (all)	21	9	4
Hyperkeratosis			

subjects affected / exposed	4 / 203 (1.97%)	0 / 64 (0.00%)	3 / 65 (4.62%)
occurrences (all)	4	0	3
Night sweats			
subjects affected / exposed	15 / 203 (7.39%)	10 / 64 (15.63%)	4 / 65 (6.15%)
occurrences (all)	24	10	4
Photosensitivity reaction			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	29 / 203 (14.29%)	6 / 64 (9.38%)	6 / 65 (9.23%)
occurrences (all)	33	6	7
Rash			
subjects affected / exposed	28 / 203 (13.79%)	3 / 64 (4.69%)	10 / 65 (15.38%)
occurrences (all)	38	4	14
Rash erythematous			
subjects affected / exposed	39 / 203 (19.21%)	21 / 64 (32.81%)	9 / 65 (13.85%)
occurrences (all)	53	27	14
Rash generalised			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	0	2	1
Rash macular			
subjects affected / exposed	9 / 203 (4.43%)	4 / 64 (6.25%)	0 / 65 (0.00%)
occurrences (all)	13	5	0
Rash maculo-papular			
subjects affected / exposed	21 / 203 (10.34%)	11 / 64 (17.19%)	4 / 65 (6.15%)
occurrences (all)	27	13	5
Rash papular			
subjects affected / exposed	14 / 203 (6.90%)	4 / 64 (6.25%)	5 / 65 (7.69%)
occurrences (all)	17	7	6
Rash pruritic			
subjects affected / exposed	21 / 203 (10.34%)	6 / 64 (9.38%)	5 / 65 (7.69%)
occurrences (all)	25	7	7
Skin disorder			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Skin exfoliation			

subjects affected / exposed	12 / 203 (5.91%)	6 / 64 (9.38%)	2 / 65 (3.08%)
occurrences (all)	13	7	2
Skin lesion			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	3 / 65 (4.62%)
occurrences (all)	4	1	3
Urticaria			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 203 (1.48%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	5	1	1
Chronic kidney disease			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	6 / 203 (2.96%)	2 / 64 (3.13%)	3 / 65 (4.62%)
occurrences (all)	6	2	3
Haematuria			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences (all)	2	0	2
Hypertonic bladder			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	7 / 203 (3.45%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	9	0	1
Renal colic			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	4	1	2
Urinary retention			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	3 / 65 (4.62%)
occurrences (all)	4	1	3

Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	7 / 203 (3.45%)	2 / 64 (3.13%)	4 / 65 (6.15%)
occurrences (all)	7	2	4
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	72 / 203 (35.47%)	18 / 64 (28.13%)	22 / 65 (33.85%)
occurrences (all)	90	22	30
Back pain			
subjects affected / exposed	50 / 203 (24.63%)	8 / 64 (12.50%)	10 / 65 (15.38%)
occurrences (all)	58	11	11
Bone pain			
subjects affected / exposed	32 / 203 (15.76%)	6 / 64 (9.38%)	8 / 65 (12.31%)
occurrences (all)	35	6	9
Flank pain			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	3 / 65 (4.62%)
occurrences (all)	2	0	3
Limb discomfort			
subjects affected / exposed	1 / 203 (0.49%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences (all)	1	3	0
Muscle spasms			
subjects affected / exposed	32 / 203 (15.76%)	6 / 64 (9.38%)	4 / 65 (6.15%)
occurrences (all)	42	6	5
Muscular weakness			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	4	1	2
Musculoskeletal pain			
subjects affected / exposed	22 / 203 (10.84%)	5 / 64 (7.81%)	4 / 65 (6.15%)
occurrences (all)	23	7	5
Myalgia			
subjects affected / exposed	47 / 203 (23.15%)	18 / 64 (28.13%)	14 / 65 (21.54%)
occurrences (all)	56	23	17
Neck pain			

subjects affected / exposed	13 / 203 (6.40%)	1 / 64 (1.56%)	3 / 65 (4.62%)
occurrences (all)	16	1	5
Osteoarthritis			
subjects affected / exposed	6 / 203 (2.96%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	7	0	0
Pain in extremity			
subjects affected / exposed	56 / 203 (27.59%)	9 / 64 (14.06%)	11 / 65 (16.92%)
occurrences (all)	83	12	12
Limb mass			
subjects affected / exposed	3 / 203 (1.48%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	3	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Breast cellulitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	19 / 203 (9.36%)	5 / 64 (7.81%)	3 / 65 (4.62%)
occurrences (all)	30	6	3
Cellulitis			
subjects affected / exposed	6 / 203 (2.96%)	1 / 64 (1.56%)	4 / 65 (6.15%)
occurrences (all)	8	1	5
Conjunctivitis			
subjects affected / exposed	9 / 203 (4.43%)	2 / 64 (3.13%)	2 / 65 (3.08%)
occurrences (all)	10	2	3
Cystitis			
subjects affected / exposed	5 / 203 (2.46%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	8	0	1
Ear infection			
subjects affected / exposed	1 / 203 (0.49%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	1	1	2
Folliculitis			
subjects affected / exposed	8 / 203 (3.94%)	6 / 64 (9.38%)	3 / 65 (4.62%)
occurrences (all)	12	6	4

Fungaemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	6 / 203 (2.96%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	7	1	3
Infection			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	11 / 203 (5.42%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	12	1	2
Lower respiratory tract infection			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	6	1	0
Mastitis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Mastoiditis			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	26 / 203 (12.81%)	7 / 64 (10.94%)	9 / 65 (13.85%)
occurrences (all)	37	8	12
Oral candidiasis			
subjects affected / exposed	4 / 203 (1.97%)	1 / 64 (1.56%)	1 / 65 (1.54%)
occurrences (all)	4	1	1
Otitis externa			
subjects affected / exposed	0 / 203 (0.00%)	2 / 64 (3.13%)	0 / 65 (0.00%)
occurrences (all)	0	2	0
Otitis media acute			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	0	1	0

Periodontitis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	2 / 203 (0.99%)	1 / 64 (1.56%)	0 / 65 (0.00%)
occurrences (all)	2	1	0
Pneumonia			
subjects affected / exposed	7 / 203 (3.45%)	1 / 64 (1.56%)	2 / 65 (3.08%)
occurrences (all)	10	1	3
Respiratory tract infection			
subjects affected / exposed	2 / 203 (0.99%)	0 / 64 (0.00%)	1 / 65 (1.54%)
occurrences (all)	2	0	1
Sinusitis			
subjects affected / exposed	17 / 203 (8.37%)	7 / 64 (10.94%)	3 / 65 (4.62%)
occurrences (all)	23	11	4
Tonsillitis			
subjects affected / exposed	4 / 203 (1.97%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	4	0	0
Tooth abscess			
subjects affected / exposed	1 / 203 (0.49%)	0 / 64 (0.00%)	2 / 65 (3.08%)
occurrences (all)	1	0	3
Tooth infection			
subjects affected / exposed	6 / 203 (2.96%)	0 / 64 (0.00%)	4 / 65 (6.15%)
occurrences (all)	7	0	4
Upper respiratory tract infection			
subjects affected / exposed	16 / 203 (7.88%)	18 / 64 (28.13%)	9 / 65 (13.85%)
occurrences (all)	24	23	13
Urinary tract infection			
subjects affected / exposed	18 / 203 (8.87%)	5 / 64 (7.81%)	9 / 65 (13.85%)
occurrences (all)	38	5	11
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	28 / 203 (13.79%)	7 / 64 (10.94%)	10 / 65 (15.38%)
occurrences (all)	29	9	12
Dehydration			

subjects affected / exposed	6 / 203 (2.96%)	4 / 64 (6.25%)	1 / 65 (1.54%)
occurrences (all)	7	5	1
Gout			
subjects affected / exposed	3 / 203 (1.48%)	5 / 64 (7.81%)	1 / 65 (1.54%)
occurrences (all)	3	5	1
Hyperamylasaemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	6 / 203 (2.96%)	4 / 64 (6.25%)	2 / 65 (3.08%)
occurrences (all)	6	4	3
Hyperglycaemia			
subjects affected / exposed	8 / 203 (3.94%)	7 / 64 (10.94%)	9 / 65 (13.85%)
occurrences (all)	11	7	10
Hyperkalaemia			
subjects affected / exposed	6 / 203 (2.96%)	3 / 64 (4.69%)	1 / 65 (1.54%)
occurrences (all)	6	3	1
Hyperuricaemia			
subjects affected / exposed	16 / 203 (7.88%)	3 / 64 (4.69%)	3 / 65 (4.62%)
occurrences (all)	21	3	4
Hypocalcaemia			
subjects affected / exposed	7 / 203 (3.45%)	1 / 64 (1.56%)	8 / 65 (12.31%)
occurrences (all)	7	2	10
Hypokalaemia			
subjects affected / exposed	12 / 203 (5.91%)	4 / 64 (6.25%)	3 / 65 (4.62%)
occurrences (all)	17	5	4
Hypomagnesaemia			
subjects affected / exposed	2 / 203 (0.99%)	2 / 64 (3.13%)	3 / 65 (4.62%)
occurrences (all)	3	2	4
Hyponatraemia			
subjects affected / exposed	10 / 203 (4.93%)	2 / 64 (3.13%)	3 / 65 (4.62%)
occurrences (all)	12	4	4
Hypophosphataemia			
subjects affected / exposed	10 / 203 (4.93%)	3 / 64 (4.69%)	3 / 65 (4.62%)
occurrences (all)	18	6	6
Iron overload			

subjects affected / exposed	0 / 203 (0.00%)	0 / 64 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 203 (0.49%)	2 / 64 (3.13%)	2 / 65 (3.08%)
occurrences (all)	1	2	2

Non-serious adverse events	Cohort D: AP-CML with T315I Mutation	Cohort E: BP-CML/Ph+ ALL R-I	Cohort F: BP-CML or Ph+ ALL with T315I Mutation
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 18 (100.00%)	48 / 48 (100.00%)	46 / 46 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	8 / 18 (44.44%)	13 / 48 (27.08%)	8 / 46 (17.39%)
occurrences (all)	10	14	8
Hypotension			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	1 / 46 (2.17%)
occurrences (all)	0	4	1
Peripheral ischaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Peripheral venous disease			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 18 (22.22%)	3 / 48 (6.25%)	8 / 46 (17.39%)
occurrences (all)	5	3	13
Chest pain			

subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Chills			
subjects affected / exposed	4 / 18 (22.22%)	7 / 48 (14.58%)	2 / 46 (4.35%)
occurrences (all)	4	7	2
Fatigue			
subjects affected / exposed	8 / 18 (44.44%)	16 / 48 (33.33%)	9 / 46 (19.57%)
occurrences (all)	9	18	10
Feeling hot			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
General physical health deterioration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences (all)	0	2	1
Localised oedema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences (all)	0	3	2
Oedema peripheral			
subjects affected / exposed	5 / 18 (27.78%)	12 / 48 (25.00%)	5 / 46 (10.87%)
occurrences (all)	7	12	5
Pain			
subjects affected / exposed	3 / 18 (16.67%)	8 / 48 (16.67%)	3 / 46 (6.52%)
occurrences (all)	3	9	3
Performance status decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0

Peripheral swelling			
subjects affected / exposed	2 / 18 (11.11%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	2	0	1
Pyrexia			
subjects affected / exposed	11 / 18 (61.11%)	16 / 48 (33.33%)	12 / 46 (26.09%)
occurrences (all)	16	18	26
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Social circumstances			
Activities of daily living impaired			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast mass			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Erectile dysfunction			
subjects affected / exposed	4 / 18 (22.22%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	5	1	0
Testicular pain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 18 (16.67%)	8 / 48 (16.67%)	6 / 46 (13.04%)
occurrences (all)	5	8	6
Dysphonia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	4 / 18 (22.22%)	11 / 48 (22.92%)	3 / 46 (6.52%)
occurrences (all)	5	13	3
Epistaxis			
subjects affected / exposed	1 / 18 (5.56%)	5 / 48 (10.42%)	3 / 46 (6.52%)
occurrences (all)	1	6	3
Nasal congestion			
subjects affected / exposed	1 / 18 (5.56%)	4 / 48 (8.33%)	2 / 46 (4.35%)
occurrences (all)	1	4	2
Oropharyngeal pain			
subjects affected / exposed	3 / 18 (16.67%)	8 / 48 (16.67%)	1 / 46 (2.17%)
occurrences (all)	5	9	3
Pharyngeal erythema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	2 / 18 (11.11%)	8 / 48 (16.67%)	4 / 46 (8.70%)
occurrences (all)	2	8	4
Productive cough			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Sleep apnoea syndrome			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 18 (22.22%)	4 / 48 (8.33%)	3 / 46 (6.52%)
occurrences (all)	4	4	3
Confusional state			
subjects affected / exposed	2 / 18 (11.11%)	2 / 48 (4.17%)	3 / 46 (6.52%)
occurrences (all)	2	2	3
Depression			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	1 / 46 (2.17%)
occurrences (all)	0	3	1

Hallucination			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 18 (5.56%)	10 / 48 (20.83%)	1 / 46 (2.17%)
occurrences (all)	3	10	1
Libido decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 18 (22.22%)	7 / 48 (14.58%)	5 / 46 (10.87%)
occurrences (all)	6	9	6
Amylase increased			
subjects affected / exposed	1 / 18 (5.56%)	4 / 48 (8.33%)	1 / 46 (2.17%)
occurrences (all)	1	6	1
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 18 (27.78%)	7 / 48 (14.58%)	6 / 46 (13.04%)
occurrences (all)	5	8	6
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	0	3	0
Blood bilirubin increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Blood cholesterol increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 18 (0.00%)	5 / 48 (10.42%)	1 / 46 (2.17%)
occurrences (all)	0	5	1
Blood glucose increased			

subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Blood triglycerides increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	4	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 18 (16.67%)	2 / 48 (4.17%)	0 / 46 (0.00%)
occurrences (all)	3	3	0
Haemoglobin decreased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	2 / 18 (11.11%)	8 / 48 (16.67%)	3 / 46 (6.52%)
occurrences (all)	2	11	4
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	3 / 18 (16.67%)	5 / 48 (10.42%)	2 / 46 (4.35%)
occurrences (all)	4	5	3
Platelet count decreased			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	3 / 46 (6.52%)
occurrences (all)	1	3	3
Platelet count increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 18 (0.00%)	5 / 48 (10.42%)	2 / 46 (4.35%)
occurrences (all)	0	5	2
White blood cell count decreased			

subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	3	0	0
Fall			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	0	3	0
Hand fracture			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Head injury			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Laceration			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Ligament sprain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	2 / 18 (11.11%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	2	1	0
Skin injury			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Subcutaneous haematoma			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Tendon rupture			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Transfusion reaction			

subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences (all)	1	2	1
Transfusion related complication			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	0	6	0
Atrial fibrillation			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	4 / 46 (8.70%)
occurrences (all)	0	2	5
Cardiac failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	0	3	0
Palpitations			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Pericardial effusion			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	2 / 46 (4.35%)
occurrences (all)	0	3	2
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	4 / 46 (8.70%)
occurrences (all)	0	2	4
Nervous system disorders			
Aphasia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Ataxia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Burning sensation			

subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Depressed level of consciousness			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	2 / 18 (11.11%)	4 / 48 (8.33%)	0 / 46 (0.00%)
occurrences (all)	2	4	0
Dysgeusia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Facial paralysis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	7 / 18 (38.89%)	15 / 48 (31.25%)	12 / 46 (26.09%)
occurrences (all)	14	19	16
Hypoaesthesia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Radiculopathy			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Somnolence			

subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Vith nerve disorder			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 18 (38.89%)	14 / 48 (29.17%)	11 / 46 (23.91%)
occurrences (all)	11	24	17
Febrile neutropenia			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	3 / 46 (6.52%)
occurrences (all)	0	3	6
Hypochromasia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	2	1	0
Leukopenia			
subjects affected / exposed	2 / 18 (11.11%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	4 / 18 (22.22%)	13 / 48 (27.08%)	7 / 46 (15.22%)
occurrences (all)	5	14	7
Thrombocytopenia			
subjects affected / exposed	4 / 18 (22.22%)	16 / 48 (33.33%)	7 / 46 (15.22%)
occurrences (all)	5	17	10
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Vertigo			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	2	1	0
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Conjunctival hyperaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	2 / 18 (11.11%)	4 / 48 (8.33%)	3 / 46 (6.52%)
occurrences (all)	2	4	3
Eye pain			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	0	3	0
Eyelid disorder			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Eyelid oedema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Visual acuity reduced			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Vitreous floaters			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			

subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Abdominal distension			
subjects affected / exposed	1 / 18 (5.56%)	3 / 48 (6.25%)	1 / 46 (2.17%)
occurrences (all)	1	4	1
Abdominal pain			
subjects affected / exposed	7 / 18 (38.89%)	7 / 48 (14.58%)	10 / 46 (21.74%)
occurrences (all)	12	7	12
Abdominal pain upper			
subjects affected / exposed	2 / 18 (11.11%)	6 / 48 (12.50%)	8 / 46 (17.39%)
occurrences (all)	2	6	9
Ascites			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Constipation			
subjects affected / exposed	7 / 18 (38.89%)	21 / 48 (43.75%)	13 / 46 (28.26%)
occurrences (all)	11	26	15
Dental necrosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	7 / 18 (38.89%)	15 / 48 (31.25%)	4 / 46 (8.70%)
occurrences (all)	10	16	4
Dry mouth			
subjects affected / exposed	0 / 18 (0.00%)	4 / 48 (8.33%)	1 / 46 (2.17%)
occurrences (all)	0	4	1
Dyspepsia			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences (all)	0	2	2
Dysphagia			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	0 / 46 (0.00%)
occurrences (all)	0	4	0
Gingival bleeding			

subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences (all)	0	2	2
Haemorrhoids			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences (all)	1	2	2
Mouth haemorrhage			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	3
Nausea			
subjects affected / exposed	5 / 18 (27.78%)	16 / 48 (33.33%)	12 / 46 (26.09%)
occurrences (all)	7	17	14
Odynophagia			
subjects affected / exposed	2 / 18 (11.11%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	2	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	3 / 46 (6.52%)
occurrences (all)	1	2	3
Toothache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	6 / 18 (33.33%)	14 / 48 (29.17%)	11 / 46 (23.91%)
occurrences (all)	6	27	14
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	4 / 18 (22.22%)	4 / 48 (8.33%)	3 / 46 (6.52%)
occurrences (all)	4	4	3
Dry skin			

subjects affected / exposed	4 / 18 (22.22%)	15 / 48 (31.25%)	9 / 46 (19.57%)
occurrences (all)	6	16	9
Ecchymosis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Erythema			
subjects affected / exposed	1 / 18 (5.56%)	3 / 48 (6.25%)	4 / 46 (8.70%)
occurrences (all)	1	3	4
Exfoliative rash			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Generalised erythema			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	3 / 46 (6.52%)
occurrences (all)	1	1	3
Hyperkeratosis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences (all)	3	2	2
Photosensitivity reaction			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences (all)	1	2	1
Rash			
subjects affected / exposed	3 / 18 (16.67%)	2 / 48 (4.17%)	3 / 46 (6.52%)
occurrences (all)	3	2	3
Rash erythematous			
subjects affected / exposed	2 / 18 (11.11%)	11 / 48 (22.92%)	8 / 46 (17.39%)
occurrences (all)	4	14	9
Rash generalised			

subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	0 / 46 (0.00%)
occurrences (all)	1	2	0
Rash maculo-papular			
subjects affected / exposed	1 / 18 (5.56%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	1	4	0
Rash papular			
subjects affected / exposed	1 / 18 (5.56%)	3 / 48 (6.25%)	1 / 46 (2.17%)
occurrences (all)	1	3	1
Rash pruritic			
subjects affected / exposed	3 / 18 (16.67%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences (all)	4	2	1
Skin disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	2
Skin lesion			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	2
Urticaria			
subjects affected / exposed	1 / 18 (5.56%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences (all)	1	2	2
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	0	4	0
Chronic kidney disease			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	2 / 18 (11.11%)	3 / 48 (6.25%)	1 / 46 (2.17%)
occurrences (all)	2	3	1

Haematuria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Hypertonic bladder			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	4	0	0
Pollakiuria			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	0	3	0
Renal colic			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Urinary incontinence			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences (all)	1	1	1
Urinary retention			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	2
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Hypothyroidism			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 18 (33.33%)	10 / 48 (20.83%)	6 / 46 (13.04%)
occurrences (all)	7	11	6
Back pain			
subjects affected / exposed	3 / 18 (16.67%)	8 / 48 (16.67%)	7 / 46 (15.22%)
occurrences (all)	3	9	7
Bone pain			
subjects affected / exposed	3 / 18 (16.67%)	8 / 48 (16.67%)	1 / 46 (2.17%)
occurrences (all)	3	8	1
Flank pain			

subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Limb discomfort			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	1 / 18 (5.56%)	3 / 48 (6.25%)	4 / 46 (8.70%)
occurrences (all)	2	3	4
Muscular weakness			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal pain			
subjects affected / exposed	2 / 18 (11.11%)	3 / 48 (6.25%)	3 / 46 (6.52%)
occurrences (all)	2	3	3
Myalgia			
subjects affected / exposed	4 / 18 (22.22%)	10 / 48 (20.83%)	3 / 46 (6.52%)
occurrences (all)	4	12	3
Neck pain			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	2 / 46 (4.35%)
occurrences (all)	0	2	2
Osteoarthritis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	2	0
Pain in extremity			
subjects affected / exposed	5 / 18 (27.78%)	6 / 48 (12.50%)	6 / 46 (13.04%)
occurrences (all)	6	6	7
Limb mass			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	2 / 46 (4.35%)
occurrences (all)	0	3	3
Breast cellulitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0

Bronchitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Cellulitis			
subjects affected / exposed	1 / 18 (5.56%)	4 / 48 (8.33%)	2 / 46 (4.35%)
occurrences (all)	1	4	2
Conjunctivitis			
subjects affected / exposed	2 / 18 (11.11%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Cystitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Ear infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	2 / 46 (4.35%)
occurrences (all)	1	1	2
Fungaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	1	0	1
Mastitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0

Mastoiditis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Nail infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 18 (27.78%)	1 / 48 (2.08%)	2 / 46 (4.35%)
occurrences (all)	6	1	2
Oral candidiasis			
subjects affected / exposed	1 / 18 (5.56%)	3 / 48 (6.25%)	1 / 46 (2.17%)
occurrences (all)	1	3	1
Otitis externa			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Otitis media acute			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Periodontitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	2 / 18 (11.11%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Pneumonia			
subjects affected / exposed	1 / 18 (5.56%)	4 / 48 (8.33%)	1 / 46 (2.17%)
occurrences (all)	1	4	1
Respiratory tract infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Tonsillitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0

Tooth abscess			
subjects affected / exposed	1 / 18 (5.56%)	1 / 48 (2.08%)	1 / 46 (2.17%)
occurrences (all)	1	1	1
Tooth infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 18 (11.11%)	6 / 48 (12.50%)	2 / 46 (4.35%)
occurrences (all)	2	10	2
Urinary tract infection			
subjects affected / exposed	3 / 18 (16.67%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences (all)	5	3	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 18 (11.11%)	7 / 48 (14.58%)	8 / 46 (17.39%)
occurrences (all)	2	7	8
Dehydration			
subjects affected / exposed	1 / 18 (5.56%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	1	3	0
Gout			
subjects affected / exposed	1 / 18 (5.56%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	1	4	0
Hyperamylasaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 48 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 18 (0.00%)	2 / 48 (4.17%)	0 / 46 (0.00%)
occurrences (all)	0	2	0
Hyperglycaemia			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	2 / 46 (4.35%)
occurrences (all)	0	3	2
Hyperkalaemia			
subjects affected / exposed	2 / 18 (11.11%)	5 / 48 (10.42%)	3 / 46 (6.52%)
occurrences (all)	2	6	3
Hyperuricaemia			

subjects affected / exposed	2 / 18 (11.11%)	5 / 48 (10.42%)	1 / 46 (2.17%)
occurrences (all)	2	5	1
Hypocalcaemia			
subjects affected / exposed	1 / 18 (5.56%)	5 / 48 (10.42%)	4 / 46 (8.70%)
occurrences (all)	1	5	4
Hypokalaemia			
subjects affected / exposed	2 / 18 (11.11%)	11 / 48 (22.92%)	4 / 46 (8.70%)
occurrences (all)	2	13	4
Hypomagnesaemia			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	1 / 46 (2.17%)
occurrences (all)	0	3	1
Hyponatraemia			
subjects affected / exposed	2 / 18 (11.11%)	2 / 48 (4.17%)	1 / 46 (2.17%)
occurrences (all)	3	2	1
Hypophosphataemia			
subjects affected / exposed	1 / 18 (5.56%)	5 / 48 (10.42%)	1 / 46 (2.17%)
occurrences (all)	1	5	1
Iron overload			
subjects affected / exposed	0 / 18 (0.00%)	3 / 48 (6.25%)	0 / 46 (0.00%)
occurrences (all)	0	3	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 48 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1

Non-serious adverse events	Unassigned AP/CP-CML		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)		
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Haemorrhage			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Hot flush			

subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	2		
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Peripheral ischaemia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Peripheral venous disease			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Chills			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Feeling hot			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
General physical health deterioration			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Hernia			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Performance status decreased			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Social circumstances			
Activities of daily living impaired			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Reproductive system and breast disorders			

Breast mass				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Erectile dysfunction				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Testicular pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Respiratory, thoracic and mediastinal disorders				
Asthma				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Catarrh				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Cough				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Dysphonia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Dyspnoea				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	2			
Epistaxis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Nasal congestion				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Oropharyngeal pain				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Pharyngeal erythema				

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	2		
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	2		
Hallucination			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Hallucination, visual			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Libido decreased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Amylase increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Aspartate aminotransferase increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Blood alkaline phosphatase increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Blood bilirubin increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Blood cholesterol increased				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Blood creatinine increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Blood glucose increased				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Blood phosphorus decreased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Blood triglycerides increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Haemoglobin decreased				

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Platelet count increased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Hand fracture			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Head injury			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Laceration			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Skin injury			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Subcutaneous haematoma			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Tendon rupture			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Transfusion related complication			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Atrial fibrillation			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Cardiac failure			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		

Cardiomyopathy subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Palpitations subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Pericardial effusion subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Tachycardia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Nervous system disorders Aphasia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Ataxia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Burning sensation subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Depressed level of consciousness subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Dizziness subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Dysgeusia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Facial paralysis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0			
Headache				

subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	2		
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Radiculopathy			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Somnolence			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Vith nerve disorder			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	2		
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Hypochromasia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		

Leukopenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		
Neutropenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 2		
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		
Vertigo subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Eye disorders Blepharitis subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1		
Cataract subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Conjunctival hyperaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Dry eye subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 2		
Eye pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0		
Eyelid disorder			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Eyelid oedema			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Visual acuity reduced			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Visual impairment			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Vitreous floaters			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Abdominal distension			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	2		
Abdominal pain upper			
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	3		
Ascites			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	3 / 5 (60.00%)		
occurrences (all)	4		

Dental necrosis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Dry mouth				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Gingival bleeding				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	2			
Haemorrhoids				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Mouth haemorrhage				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	2			
Odynophagia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Rectal haemorrhage				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			

Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	4 / 5 (80.00%)		
occurrences (all)	6		
Ecchymosis			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Exfoliative rash			
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	2		
Generalised erythema			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	3		
Hyperhidrosis			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Hyperkeratosis			

subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Night sweats				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Photosensitivity reaction				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Rash				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Rash erythematous				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Rash generalised				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Rash macular				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Rash maculo-papular				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Rash papular				
subjects affected / exposed	2 / 5 (40.00%)			
occurrences (all)	2			
Rash pruritic				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Skin disorder				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Skin exfoliation				

subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Skin lesion			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Chronic kidney disease			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Hypertonic bladder			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Renal colic			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Urinary incontinence			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		

Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Hypothyroidism			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	2		
Back pain			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	3		
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Limb discomfort			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	2		
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	3		
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Neck pain			

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Osteoarthritis			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Limb mass			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Breast cellulitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	2		
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	2		

Fungaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Mastitis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Mastoiditis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Nail infection				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	2			
Oral candidiasis				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Otitis media acute				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			

Periodontitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Tooth abscess			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Tooth infection			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	2 / 5 (40.00%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Dehydration			

subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Gout				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	2			
Hyperamylasaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Hypercholesterolaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Hyperglycaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Hyperkalaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Hyperuricaemia				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Hypocalcaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Hypokalaemia				
subjects affected / exposed	1 / 5 (20.00%)			
occurrences (all)	1			
Hypomagnesaemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Hyponatraemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Hypophosphataemia				
subjects affected / exposed	0 / 5 (0.00%)			
occurrences (all)	0			
Iron overload				

subjects affected / exposed	0 / 5 (0.00%)		
occurrences (all)	0		
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 5 (20.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 October 2010	The purposes of Protocol Amendment 1 were to: • Mandate examination of 20 metaphases for participant inclusion. • Clarify number of days within which prior treatments were allowed prior to first dose of ponatinib considering the phase of disease. • Update schedule of events and corresponding footnotes for EOT assessments. • Provide clarification on use of dose modification guidelines for AEs attributable to study drug. • Update guidance on dose modification for pancreatitis attributable to study drug in accordance with NCI CTCAE v4. • Include guidance on dose modification for QT prolongation (corrected by Fridericia formula; QTcF) attributable to study drug in accordance with NCI CTCAE v4. • Provide recommendation for ECG monitoring when a participant was taking concomitant medications known to prolong QTc interval. • Update Attachment A – response criteria.
08 April 2011	The purposes of Protocol Amendment 2 were to: • Increase overall sample size of the study to allow for over-enrollment in the R/I cohorts to ensure full participant enrollment in the T315I cohorts. • Incorporate details from an administrative letter that was prepared and submitted to investigative sites in March 2011 to clarify concomitant use and administration of hydroxyurea and anagrelide.
24 May 2012	The purposes of Protocol Amendment 3 were to: • Extend the duration of treatment beyond the original plan of 2 years. • Decrease the number of study assessments after the initial 2 years of treatment. • To make other clarifications based on regulatory updates, new information.
27 March 2013	The purposes of Protocol Amendment 4 were to: • Adverse Events of Special Interest (AESIs) were added and defined. The list of AESIs was developed based on a growing understanding of the drug's safety profile gathered from ongoing ponatinib clinical studies and experience from the expanded access program. AESIs are reported to the sponsor in the same manner as SAEs, regardless of whether they meet the regulatory definition of seriousness. • Language on drug-drug interactions was updated to reflect results of drug-drug interaction studies. • The dose modification table for ponatinib was aligned with other studies. • The bone marrow (BM) assessment schedule was modified to allow greater participant convenience in later cycles, while maintaining close assessment of clinical benefit. • Treatment administration was updated to reflect the fact that food does not affect the PK profile of ponatinib.

03 April 2015	The purposes of Protocol Amendment 5 were to: • Provide recommendations to investigators for ponatinib dose reduction based on response, to minimize the risk of AEs with ponatinib while maintaining response. These dose reduction recommendations were implemented via direct communication to investigators. • Provide updated information on the management of adverse drug reactions, including vascular occlusion, neuropathy, cardiac failure, and other events. The updated information included both the nature of the risks and recommendations for management of these events. • Provide an updated section on AESIs, updating the list of events considered AESIs and clarifying investigator's reporting responsibilities. • Provide information on multivariate analyses performed on AP24534-10-201 study data, which sought to explore the impact of dose intensity and several prognostic and predictive factors on clinical responses, AEs, and laboratory changes. • Provide updated guidelines for ponatinib dose modification for management of AEs attributable to study drug. • Revise the criteria for study discontinuation to include MI, stroke, or urgent revascularization, unless the benefit of study drug was believed to outweigh the risk, as determined by the investigator. • Provide guidance to the investigator on optimization of management of HTN and diabetes to decrease the risk of VOEs for participants taking ponatinib. • Add the definition of overdose and how to handle overdoses per standard reporting guidelines. • Provide an update of the ponatinib development program.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported