



Clinical trial results:

A Phase II, single arm, open label study of treatment-free remission (TFR) in chronic myeloid leukemia (CML) chronic phase (CP) patients after achieving sustained MR4.5 on nilotinib.

Summary

EudraCT number	2012-003186-18
Trial protocol	ES DE BE GR GB FR
Global end of trial date	29 January 2025

Results information

Result version number	v1 (current)
This version publication date	08 February 2026
First version publication date	08 February 2026

Trial information

Trial identification

Sponsor protocol code	CAMN107A2408
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01698905
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharmaceuticals
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharmaceuticals, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharmaceuticals, 41 613241111, novartis.email@novartis.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	29 January 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to evaluate the percentage of patients in Treatment-free remission (TFR) within 48-weeks following nilotinib cessation.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.nov> for complete trial results.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 December 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 6
Country: Number of subjects enrolled	Australia: 9
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Brazil: 26
Country: Number of subjects enrolled	Canada: 12
Country: Number of subjects enrolled	France: 11
Country: Number of subjects enrolled	Germany: 13
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Greece: 7
Country: Number of subjects enrolled	Israel: 8
Country: Number of subjects enrolled	Japan: 15
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Mexico: 1
Country: Number of subjects enrolled	Poland: 7
Country: Number of subjects enrolled	Russian Federation: 13
Country: Number of subjects enrolled	Singapore: 1
Country: Number of subjects enrolled	Spain: 15

Country: Number of subjects enrolled	United States: 12
Worldwide total number of subjects	163
EEA total number of subjects	54

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)	123
From 65 to 84 years	38
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Recruitment for the study comprised a total of 163 participants, who were enrolled at 63 clinical sites distributed across 18 different countries..

Pre-assignment

Screening details:

Informed consent was obtained from each participant in writing before screening before any study specific procedure was performed.

Period 1

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

Arms

Arm title	NTCS phase
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Arm description:

Patients with minimum 3 years of tyrosine kinase inhibitor treatment (first with imatinib and then switched to nilotinib) since initial diagnosis, at least 2 years of nilotinib treatment prior to study entry and who achieved MR4.5 (local laboratory assessment) during nilotinib treatment, and determined by a Novartis designated central PCR lab assessment at screening

Arm type	Experimental
Investigational medicinal product name	Nilotinib
Investigational medicinal product code	AMN107
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Nilotinib was administered to the patients, orally at 300 mg b.i.d. or 400 mg b.i.d. during the treatment phases of the study

Number of subjects in period 1	NTCS phase
Started	163
TFR Phase	126 ^[1]
NTRI Phase	61 ^[2]
NTCT Phase	26 ^[3]
TFR-2 Phase	7 ^[4]
NTRI-2 Phase	2 ^[5]
NTCT-P Phase	14 ^[6]
Completed	152
Not completed	11
Adverse event, serious fatal	1
Physician decision	1

Adverse event, non-fatal	5
Pregnancy	1
Subject/guardian decision	2
Protocol deviation	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The duration of the TFR phase was up to 528 weeks after the last patient entered the TFR phase. Patients stopped taking nilotinib on the day they entered TFR phase.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Nilotinib treatment re-initiation (NTRI) phase: If a patient had a confirmed loss of MR4 (two consecutive BCR-ABL1 >0.01% IS) or loss of MMR (BCR-ABL1 >0.1% IS) in the TFR phase, the patient restarted nilotinib treatment.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Patients who were not eligible to enter into the TFR phase after completing the first 52-week NTCS phase entered the nilotinib treatment continuation (NTCT) phase and would continue treatment with nilotinib for another 52 weeks (a total of 104 weeks of treatment).

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Patients who maintained MR4.5 during the NTCT phase (a total of 104 weeks of treatment) were eligible to cease nilotinib treatment and enter the TFR-2 phase. The duration of the TFR-2 phase was up to 528 weeks after the last patient entered the TFR phase.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: If a patient had a loss of MMR or a confirmed loss of MR4 during the TFR-2 phase, he/she entered the nilotinib treatment re-initiation-2 (NTRI-2) phase and resume nilotinib treatment at a dose of either 300 mg or 400 mg b.i.d. The frequency of assessments for the NTRI-2 phase was similar to those of the NTRI phase.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Patients who were not able to maintain MR4.5 and had a confirmed loss of MR4.5 during the NTCT phase were not eligible to enter the TFR-2 phase. These patients entered into the nilotinib treatment prolonged continuation phase (NTCT-P) and continued nilotinib treatment until 528 weeks after the last patient entered the TFR phase, or until the patients experience unacceptable toxicity, disease progression, death, lost to follow-up.

Baseline characteristics

Reporting groups

Reporting group title	NTCS phase
Reporting group description:	
Patients with minimum 3 years of tyrosine kinase inhibitor treatment (first with imatinib and then switched to nilotinib) since initial diagnosis, at least 2 years of nilotinib treatment prior to study entry and who achieved MR4.5 (local laboratory assessment) during nilotinib treatment, and determined by a Novartis designated central PCR lab assessment at screening	

Reporting group values	NTCS phase	Total	
Number of subjects	163	163	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	123	123	
From 65-84 years	38	38	
85 years and over	2	2	
Age Continuous			
Units: years			
arithmetic mean	54.3		
standard deviation	± 13.99	-	
Sex: Female, Male			
Units: participants			
Female	86	86	
Male	77	77	
Race/Ethnicity, Customized			
Units: Subjects			
Caucasian	127	127	
Black	6	6	
Asian	23	23	
Native American	1	1	
Other	6	6	

End points

End points reporting groups

Reporting group title	NTCS phase
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Reporting group description:

Patients with minimum 3 years of tyrosine kinase inhibitor treatment (first with imatinib and then switched to nilotinib) since initial diagnosis, at least 2 years of nilotinib treatment prior to study entry and who achieved MR4.5 (local laboratory assessment) during nilotinib treatment, and determined by a Novartis designated central PCR lab assessment at screening

Subject analysis set title	TFR phase
Subject analysis set type	Full analysis

Subject analysis set description:

TFR is defined as no confirmed loss of MR4 (Molecular response 4.0 log reduction from baseline) or loss of MMR (major molecular response) and no re-starting of nilotinib therapy within 12 months following cessation of nilotinib. Confirmed loss of MR4 is two consecutive BCR-ABL > 0.01% IS. Loss of MMR does not require confirmation.

Subject analysis set title	TFS phase
Subject analysis set type	Full analysis

Subject analysis set description:

TFR is defined as no confirmed loss of MR4 (Molecular response 4.0 log reduction from baseline) or loss of MMR (major molecular response) and no re-starting of nilotinib therapy within 12 months following cessation of nilotinib. Confirmed loss of MR4 is two consecutive BCR-ABL > 0.01% IS. Loss of MMR does not require confirmation.

Subject analysis set title	NTRI phase
Subject analysis set type	Safety analysis

Subject analysis set description:

If a patient had a confirmed loss of MR4 (two consecutive BCR-ABL1 >0.01% IS) or loss of MMR (BCR-ABL1 >0.1% IS) in the TFR phase, the patient restarted nilotinib treatment.

Subject analysis set title	NTRI phase
Subject analysis set type	Safety analysis

Subject analysis set description:

If a patient had a confirmed loss of MR4 (two consecutive BCR-ABL1 >0.01% IS) or loss of MMR (BCR-ABL1 >0.1% IS) in the TFR phase, the patient restarted nilotinib treatment.

Subject analysis set title	NTRI phase
Subject analysis set type	Safety analysis

Subject analysis set description:

If a patient had a confirmed loss of MR4 (two consecutive BCR-ABL1 >0.01% IS) or loss of MMR (BCR-ABL1 >0.1% IS) in the TFR phase, the patient restarted nilotinib treatment.

Subject analysis set title	NTRI phase
Subject analysis set type	Safety analysis

Subject analysis set description:

If a patient had a confirmed loss of MR4 (two consecutive BCR-ABL1 >0.01% IS) or loss of MMR (BCR-ABL1 >0.1% IS) in the TFR phase, the patient restarted nilotinib treatment.

Primary: Percentage of participants in TFR within 48-weeks following nilotinib cessation

End point title	Percentage of participants in TFR within 48-weeks following nilotinib cessation ^[1]
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End point description:

TFR is defined as no confirmed loss of MR4 (Molecular response 4.0 log reduction from baseline) or loss of MMR (major molecular response) and no re-starting of nilotinib therapy within 12 months following cessation of nilotinib. Confirmed loss of MR4 is two consecutive BCR-ABL > 0.01% IS. Loss of MMR does not require confirmation.

End point type	Primary
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End point timeframe:

first 48 weeks following nilotinib cessation

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: No statistical analysis was planned for this primary outcome

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	126			
Units: participants	73			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in TFR within 96, 144, 192, 264 weeks, and within the end of years 6, 7, 8, 9 and 10 following nilotinib cessation

End point title	Percentage of participants in TFR within 96, 144, 192, 264 weeks, and within the end of years 6, 7, 8, 9 and 10 following nilotinib cessation
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End point description:

TFR is defined as no confirmed loss of MR4 (molecular response 4.0 log reduction from baseline) or loss of MMR (major molecular response) and no re-starting of nilotinib therapy within 12 months following cessation of nilotinib. Confirmed loss of MR4 is two consecutive BCR-ABL > 0.01% IS. Loss of MMR does not require confirmation.

End point type	Secondary
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End point timeframe:

first 96, 144, 192, 264 weeks, and within the end of years 6, 7, 8, 9 and 10 following nilotinib cessation.

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	126			
Units: participants				
Week 96	67			
Week 144	61			
Week 192	58			
Week 264	54			
Week 312	50			
Week 360	44			
Week 408	41			
Week 468	38			
Week 528	32			

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment free survival (TFS) after the start of the TFR phase

End point title	Treatment free survival (TFS) after the start of the TFR phase
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End point description:

Treatment-free survival defined as the time from the date of start of TFR to the date of earliest occurrence of any of the following events: loss of MMR, confirmed loss of MR4, re-initiation of nilotinib treatment due to any cause, progression to acute phase (AP) or blast crisis (BC) or death due to any cause.

End point type	Secondary
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End point timeframe:

nilotinib cessation up to approximately 580 weeks

End point values	TFS phase			
Subject group type	Subject analysis set			
Number of subjects analysed	126			
Units: Weeks				
median (confidence interval 95%)	169 (27.9 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression free survival (PFS) after the start of the TFR phase

End point title	Progression free survival (PFS) after the start of the TFR phase
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End point description:

Progression free survival, defined as the time from the date of start of TFR to the date of event defined as the first occurrence of documented disease progression to Accelerated phase/Blast Crises (AP/BC) or the date of death from any cause.

End point type	Secondary
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End point timeframe:

nilotinib cessation up to approximately 580 weeks

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	126			
Units: Weeks				
median (confidence interval 95%)	999 (999 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival (OS) after the start of the TFR phase

End point title	Overall survival (OS) after the start of the TFR phase
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End point description:

Overall survival, defined as the time from start date of TFR (date of entering the TFR phase) to date of death due to any cause at any time during the study, including the follow-up period after discontinuation of study up to LPLV. If a patient is not known to have died, survival will be censored at the date of last contact.

End point type	Secondary
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End point timeframe:

nilotinib cessation up to approximately 580 weeks

End point values	TFS phase			
Subject group type	Subject analysis set			
Number of subjects analysed	126			
Units: Weeks				
median (confidence interval 95%)	999 (999 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: BCR-ABL ratio (%) over time in nilotinib treatment re-initiation phase (NTRI)

End point title	BCR-ABL ratio (%) over time in nilotinib treatment re-initiation phase (NTRI)
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End point description:

Descriptive statistics of BCR-ABL over time after re-start of nilotinib therapy. ABL= Abelson leukemia virus and BCR=Break point cluster region.

End point type	Secondary
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End point timeframe:

re-start of nilotinib up to approximately 48 weeks

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	61			
Units: Percent				
arithmetic mean (standard deviation)				
Baseline	1.53342 (± 8.070454)			
Week 4	1.01436 (± 4.354164)			

Week 8	0.44840 (± 2.571063)			
Week 12	0.29952 (± 2.232066)			
Week 16	0.33012 (± 2.481822)			
Week 20	0.18411 (± 1.330561)			
Week 24	0.00377 (± 0.013461)			
Week 36	0.01599 (± 0.106080)			
Week 48	0.02040 (± 0.132190)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with stable MMR in nilotinib re-initiation phase

End point title	Percentage of participants with stable MMR in nilotinib re-initiation phase
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End point description:

Percentage of participants who were in stable MMR (stable MMR=BCR-ABL ≤ 0.1% IS) at multiple timepoints after achievement of that response in the nilotinib re-initiation phase for those timepoints.

End point type	Secondary
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End point timeframe:

at 48 weeks, 96 weeks, 144 weeks, 192 weeks, 240 weeks, 288 weeks, 336 weeks, 384 weeks and 432 weeks

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	60			
Units: participants				
Stable MMR for 48 weeks	52			
Stable MMR for 96 weeks	46			
Stable MMR for 144 weeks	41			
Stable MMR for 192 weeks	38			
Stable MMR for 240 weeks	31			
Stable MMR for 288 weeks	27			
Stable MMR for 336 weeks	24			
Stable MMR for 384 weeks	22			
Stable MMR for 432 weeks [18			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with stable MR4.5 in nilotinib re-initiation phase

End point title	Percentage of participants with stable MR4.5 in nilotinib re-initiation phase
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End point description:

Percentage of participants who were in stable MR4.5 (stable MR4.5=BCR-ABL \leq 0.0032% IS) at multiple timepoints after achievement of that response in the nilotinib re-initiation phase for those timepoints.

End point type	Secondary
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End point timeframe:

at 48 weeks, 96 weeks, 144 weeks, 192 weeks, 240 weeks, 288 weeks, 336 weeks, 384 weeks and 432 weeks

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	57			
Units: participants				
Stable MR4.5 for 48 weeks	46			
Stable MR4.5 for 96 weeks	43			
Stable MR4.5 for 144 weeks	39			
Stable MR4.5 for 192 weeks	35			
Stable MR4.5 for 240 weeks	29			
Stable MR4.5 for 288 weeks	25			
Stable MR4.5 for 336 weeks	23			
Stable MR4.5 for 384 weeks	21			
Stable MR4.5 for 432 weeks	18			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with stable MR4 in nilotinib re-initiation phase

End point title	Percentage of participants with stable MR4 in nilotinib re-initiation phase
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End point description:

Percentage of participants who were in stable MR4 (stable MR4=BCR-ABL \leq 0.01% IS) at multiple timepoints after achievement of that response in the nilotinib re-initiation phase for those timepoints.

End point type	Secondary
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End point timeframe:

at 48 weeks, 96 weeks, 144 weeks, 192 weeks, 240 weeks, 288 weeks, 336 weeks, 384 weeks and 432 weeks

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	58			
Units: participants				
Stable MR4 for 48 weeks	48			
Stable MR4 for 96 weeks	44			
Stable MR4 for 144 weeks	40			
Stable MR4 for 192 weeks	36			
Stable MR4 for 240 weeks	30			
Stable MR4 for 288 weeks	26			
Stable MR4 for 336 weeks	23			
Stable MR4 for 384 weeks	21			
Stable MR4 for 432 weeks	18			

Statistical analyses

No statistical analyses for this end point

Post-hoc: All collected deaths on treatment and post-treatment follow up phase

End point title	All collected deaths on treatment and post-treatment follow up phase
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End point description:

This endpoint reports all the deaths that occurred during the course of the study. During the post-treatment follow-up phase, only deaths were collected: other adverse events were not collected.

End point type	Post-hoc
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End point timeframe:

throughout the study, up to approximately 528 weeks

End point values	NTCS phase			
Subject group type	Reporting group			
Number of subjects analysed	163			
Units: participants				
On-treatment deaths	5			
Post-treatment follow up phase deaths	7			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from first dose nilotinib through up to 528 weeks (approximately 10 years) of study participation.

Adverse event reporting additional description:

Any sign or symptom that occurs from first dose nilotinib through up to 528 weeks (approximately 10 years) of study participation.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	Nilotinib treatment consolidation (NTCS) phase
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Reporting group description:

Patients who should have satisfied all the inclusion and none of the exclusion criteria were to be enrolled into the consolidation phase where the patients were treated with nilotinib with the same dose as prior to study entry. Duration of the consolidation phase was 52 weeks or until a patient experienced unacceptable toxicity, disease progression, death, loss to follow-up, and/or treatment was discontinued at the discretion of the Investigator or due to withdrawal of consent.

Reporting group title	Nilotinib treatment-free remission (TFR) phase
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Reporting group description:

The duration of the TFR phase was up to 528 weeks after the last patient entered the TFR phase. Patients stopped taking nilotinib on the day they entered TFR phase.

Reporting group title	Nilotinib treatment re-initiation (NTRI) phase
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Reporting group description:

Nilotinib treatment re-initiation (NTRI) phase: If a patient had a confirmed loss of MR4 (two consecutive BCR-ABL1 >0.01% IS) or loss of MMR (BCR-ABL1 >0.1% IS) in the TFR phase, the patient restarted nilotinib treatment.

Reporting group title	Nilotinib treatment continuation (NTCT) phase
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Reporting group description:

Patients who were not eligible to enter into the TFR phase after completing the first 52-week NTCS phase entered the nilotinib treatment continuation (NTCT) phase and would continue treatment with nilotinib for another 52 weeks (a total of 104 weeks of treatment).

Reporting group title	Nilotinib treatment re-initiation-2 phase (NTRI-2)
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Reporting group description:

If a patient had a loss of MMR or a confirmed loss of MR4 during the TFR-2 phase, he/she entered the nilotinib treatment re-initiation-2 (NTRI-2) phase and resume nilotinib treatment at a dose of either 300 mg or 400 mg b.i.d. The frequency of assessments for the NTRI-2 phase was similar to those of the NTRI phase

Reporting group title	Nilotinib treatment-free remission - 2 Phase (TRF-2)
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Reporting group description:

Patients who maintained MR4.5 during the NTCT phase (a total of 104 weeks of treatment) were eligible to cease nilotinib treatment and enter the TFR-2 phase. The duration of the TFR-2 phase was up to 528 weeks after the last patient entered the TFR phase.

Reporting group title	Nilotinib treatment prolonged continuation phase (NTCT-P)
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Reporting group description:

Patients who were not able to maintain MR4.5 and had a confirmed loss of MR4.5 during the NTCT phase were not eligible to enter the TFR-2 phase. These patients entered into the nilotinib treatment prolonged continuation phase (NTCT-P) and continued nilotinib treatment until 528 weeks after the last patient entered the TFR phase, or until the patients experience unacceptable toxicity, disease progression, death, lost to follow-up.

Reporting group title	All patients
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Reporting group description:

Participants who received study treatment and were monitored for adverse events during the on-

Serious adverse events	Nilotinib treatment consolidation (NTCS) phase	Nilotinib treatment-free remission (TFR) phase	Nilotinib treatment re-initiation (NTRI) phase
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 163 (12.88%)	34 / 126 (26.98%)	27 / 61 (44.26%)
number of deaths (all causes)	1	3	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Lung adenocarcinoma			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Lymphoproliferative disorder			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Polycythaemia vera			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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

Prostate cancer			
subjects affected / exposed	0 / 163 (0.00%)	2 / 126 (1.59%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
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			
Arterial occlusive disease			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential hypertension			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Giant cell arteritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peripheral arterial occlusive disease subjects affected / exposed	2 / 163 (1.23%)	0 / 126 (0.00%)	3 / 61 (4.92%)
occurrences causally related to treatment / all	3 / 3	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prosthetic cardiac valve stenosis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Immune system disorders			
Contrast media reaction			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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, thoracic and mediastinal disorders			

Acute pulmonary oedema			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Bronchospasm			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Pleural effusion			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Pleural fibrosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			

subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Investigations			
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Haematology test abnormal			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Transaminases increased			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
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			
Contusion			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Craniofacial fracture			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Fall			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Femoral neck fracture			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Hand fracture			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Hip fracture			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Joint dislocation			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Ligament sprain			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Meniscus injury			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			

subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Rib fracture			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Skin abrasion			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Tendon rupture			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemorrhage			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	2 / 163 (1.23%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			

subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	2 / 163 (1.23%)	7 / 126 (5.56%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 3	0 / 10	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrioventricular block			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Atrial flutter			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 163 (0.00%)	2 / 126 (1.59%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bradycardia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			

subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
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	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocardial infarction			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	3 / 61 (4.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Palpitations			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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			
Carotid artery stenosis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Cerebral artery stenosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			

subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Hepatic encephalopathy			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
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 stroke			
subjects affected / exposed	1 / 163 (0.61%)	1 / 126 (0.79%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	2 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic stroke			

subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
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			
Leukocytosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
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 pain			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Diarrhoea			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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

Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Duodenal ulcer perforation			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 163 (0.00%)	2 / 126 (1.59%)	0 / 61 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Ureterolithiasis			

subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 163 (0.61%)	1 / 126 (0.79%)	0 / 61 (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
Arthralgia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Muscle spasms			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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 chest pain			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 163 (0.00%)	3 / 126 (2.38%)	0 / 61 (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
Musculoskeletal pain			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Pain in extremity			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Polymyalgia rheumatica			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 163 (0.00%)	2 / 126 (1.59%)	0 / 61 (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
Spinal osteoarthritis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
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 stenosis			

subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Spondylolisthesis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
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			
Cellulitis			
subjects affected / exposed	1 / 163 (0.61%)	2 / 126 (1.59%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Diverticulitis			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Gastroenteritis			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Influenza			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (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
Pelvic inflammatory disease			

subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 163 (1.23%)	4 / 126 (3.17%)	2 / 61 (3.28%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
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 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (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

Serious adverse events	Nilotinib treatment continuation (NTCT) phase	Nilotinib treatment re-initiation-2 phase (NTRI-2)	Nilotinib treatment-free remission - 2 Phase (TRF-2)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 26 (11.54%)	2 / 2 (100.00%)	3 / 7 (42.86%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 adenocarcinoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoproliferative disorder			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycythaemia vera			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (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 disorders			
Arterial occlusive disease			
subjects affected / exposed	0 / 26 (0.00%)	1 / 2 (50.00%)	0 / 7 (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
Essential hypertension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giant cell arteritis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
Non-cardiac chest pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prosthetic cardiac valve stenosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
Contrast media reaction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
Intermenstrual bleeding			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 fibrosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 congestion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematology test abnormal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (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
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniofacial fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 abrasion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
Angina pectoris			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 myocardial infarction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 fibrillation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 26 (0.00%)	1 / 2 (50.00%)	0 / 7 (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
Cardiopulmonary failure			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid artery stenosis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 stroke			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 encephalopathy			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic stroke			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
Leukocytosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
Cataract			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
Hyperthyroidism			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intervertebral disc disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasms			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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			
Cellulitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic inflammatory disease			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (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			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
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	Nilotinib treatment prolonged continuation phase (NTCT-P)	All patients	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 14 (35.71%)	80 / 163 (49.08%)	
number of deaths (all causes)	0	5	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma metastatic			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoproliferative disorder			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia vera			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Arterial occlusive disease			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Giant cell arteritis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 14 (0.00%)	5 / 163 (3.07%)	
occurrences causally related to treatment / all	0 / 0	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration			

site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic cardiac valve stenosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Contrast media reaction			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural fibrosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Investigations			
Anticoagulation drug level above therapeutic			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematology test abnormal			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniofacial fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin abrasion			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	9 / 163 (5.52%)	
occurrences causally related to treatment / all	0 / 0	1 / 14	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrioventricular block			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bradycardia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocardial infarction			

subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery stenosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences causally related to treatment / all	0 / 0	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic stroke			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			

subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IgA nephropathy			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diverticulitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic inflammatory disease			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	7 / 163 (4.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Nilotinib treatment consolidation (NTCS) phase	Nilotinib treatment-free remission (TFR) phase	Nilotinib treatment re-initiation (NTRI) phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	103 / 163 (63.19%)	93 / 126 (73.81%)	56 / 61 (91.80%)
Vascular disorders			
Hypertension			
subjects affected / exposed	13 / 163 (7.98%)	23 / 126 (18.25%)	19 / 61 (31.15%)
occurrences (all)	16	26	23
Angiopathy			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 163 (1.23%)	4 / 126 (3.17%)	2 / 61 (3.28%)
occurrences (all)	2	5	2
Chest discomfort			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	3 / 61 (4.92%)
occurrences (all)	0	1	3
Cyst			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	1 / 163 (0.61%)	3 / 126 (2.38%)	2 / 61 (3.28%)
occurrences (all)	1	3	2
Oedema peripheral			
subjects affected / exposed	3 / 163 (1.84%)	9 / 126 (7.14%)	3 / 61 (4.92%)
occurrences (all)	3	10	3
Non-cardiac chest pain			

subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	3 / 126 (2.38%) 3	3 / 61 (4.92%) 4
Fatigue subjects affected / exposed occurrences (all)	6 / 163 (3.68%) 6	7 / 126 (5.56%) 7	8 / 61 (13.11%) 9
Pyrexia subjects affected / exposed occurrences (all)	3 / 163 (1.84%) 4	4 / 126 (3.17%) 4	2 / 61 (3.28%) 2
Reproductive system and breast disorders Heavy menstrual bleeding subjects affected / exposed occurrences (all)	2 / 163 (1.23%) 2	2 / 126 (1.59%) 4	1 / 61 (1.64%) 1
Menopausal symptoms subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Menstruation irregular subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	1 / 61 (1.64%) 1
Dyspnoea subjects affected / exposed occurrences (all)	3 / 163 (1.84%) 5	5 / 126 (3.97%) 7	3 / 61 (4.92%) 4
Cough subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	8 / 126 (6.35%) 13	5 / 61 (8.20%) 5
Oropharyngeal pain subjects affected / exposed occurrences (all)	3 / 163 (1.84%) 3	2 / 126 (1.59%) 2	3 / 61 (4.92%) 3
Sinus disorder subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Psychiatric disorders			

Anxiety			
subjects affected / exposed	2 / 163 (1.23%)	6 / 126 (4.76%)	1 / 61 (1.64%)
occurrences (all)	2	6	1
Depression			
subjects affected / exposed	0 / 163 (0.00%)	5 / 126 (3.97%)	1 / 61 (1.64%)
occurrences (all)	0	5	1
Insomnia			
subjects affected / exposed	4 / 163 (2.45%)	5 / 126 (3.97%)	3 / 61 (4.92%)
occurrences (all)	4	7	3
Stress			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 163 (1.23%)	5 / 126 (3.97%)	7 / 61 (11.48%)
occurrences (all)	2	5	9
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 163 (1.23%)	4 / 126 (3.17%)	6 / 61 (9.84%)
occurrences (all)	2	4	9
Blood bilirubin increased			
subjects affected / exposed	2 / 163 (1.23%)	0 / 126 (0.00%)	6 / 61 (9.84%)
occurrences (all)	2	0	11
Blood cholesterol increased			
subjects affected / exposed	1 / 163 (0.61%)	4 / 126 (3.17%)	2 / 61 (3.28%)
occurrences (all)	1	4	2
Blood creatinine increased			
subjects affected / exposed	3 / 163 (1.84%)	6 / 126 (4.76%)	2 / 61 (3.28%)
occurrences (all)	3	6	3
Blood potassium decreased			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur			

subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 163 (0.61%)	2 / 126 (1.59%)	2 / 61 (3.28%)
occurrences (all)	1	2	2
Lipase increased			
subjects affected / exposed	4 / 163 (2.45%)	3 / 126 (2.38%)	4 / 61 (6.56%)
occurrences (all)	7	3	12
Serum ferritin decreased			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Vitamin D decreased			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 163 (0.00%)	15 / 126 (11.90%)	3 / 61 (4.92%)
occurrences (all)	0	16	3
Weight decreased			
subjects affected / exposed	4 / 163 (2.45%)	4 / 126 (3.17%)	4 / 61 (6.56%)
occurrences (all)	4	4	5
Injury, poisoning and procedural complications			
Arthropod sting			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Epicondylitis			
subjects affected / exposed	1 / 163 (0.61%)	2 / 126 (1.59%)	1 / 61 (1.64%)
occurrences (all)	1	2	1
Expired product administered			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	2 / 61 (3.28%)
occurrences (all)	0	0	2
Fall			
subjects affected / exposed	1 / 163 (0.61%)	5 / 126 (3.97%)	3 / 61 (4.92%)
occurrences (all)	1	6	3
Incision site haematoma			

subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	1 / 163 (0.61%)	1 / 126 (0.79%)	4 / 61 (6.56%)
occurrences (all)	1	1	5
Procedural pain			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	2 / 61 (3.28%)
occurrences (all)	0	1	2
Skin abrasion			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Tendon injury			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	5 / 61 (8.20%)
occurrences (all)	0	0	5
Palpitations			
subjects affected / exposed	2 / 163 (1.23%)	2 / 126 (1.59%)	5 / 61 (8.20%)
occurrences (all)	2	3	5
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Carotid artery stenosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular stenosis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 163 (1.23%)	7 / 126 (5.56%)	5 / 61 (8.20%)
occurrences (all)	2	9	6
Dysaesthesia			

subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	1 / 61 (1.64%)
occurrences (all)	0	1	1
Headache			
subjects affected / exposed	8 / 163 (4.91%)	8 / 126 (6.35%)	8 / 61 (13.11%)
occurrences (all)	8	10	12
Facial paresis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gait spastic			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hemiplegia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	1 / 163 (0.61%)	4 / 126 (3.17%)	3 / 61 (4.92%)
occurrences (all)	1	5	3
Syncope			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	2 / 61 (3.28%)
occurrences (all)	0	1	2
Paraesthesia			
subjects affected / exposed	3 / 163 (1.84%)	1 / 126 (0.79%)	4 / 61 (6.56%)
occurrences (all)	3	1	6
Blood and lymphatic system disorders			
Increased tendency to bruise			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	2 / 163 (1.23%)	8 / 126 (6.35%)	7 / 61 (11.48%)
occurrences (all)	2	10	10

Iron deficiency anaemia subjects affected / exposed occurrences (all)	2 / 163 (1.23%) 2	2 / 126 (1.59%) 2	1 / 61 (1.64%) 8
Leukocytosis subjects affected / exposed occurrences (all)	2 / 163 (1.23%) 2	2 / 126 (1.59%) 2	0 / 61 (0.00%) 0
Eye disorders Cataract subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	3 / 126 (2.38%) 5	4 / 61 (6.56%) 4
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	6 / 163 (3.68%) 7	8 / 126 (6.35%) 9	8 / 61 (13.11%) 9
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	3 / 163 (1.84%) 3	8 / 126 (6.35%) 9	4 / 61 (6.56%) 4
Dyspepsia subjects affected / exposed occurrences (all)	4 / 163 (2.45%) 5	3 / 126 (2.38%) 3	3 / 61 (4.92%) 3
Diarrhoea subjects affected / exposed occurrences (all)	4 / 163 (2.45%) 4	8 / 126 (6.35%) 9	5 / 61 (8.20%) 7
Dental caries subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	0 / 126 (0.00%) 0	1 / 61 (1.64%) 1
Constipation subjects affected / exposed occurrences (all)	5 / 163 (3.07%) 5	4 / 126 (3.17%) 5	11 / 61 (18.03%) 12
Vomiting subjects affected / exposed occurrences (all)	5 / 163 (3.07%) 5	4 / 126 (3.17%) 6	7 / 61 (11.48%) 10
Toothache			

subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	1 / 126 (0.79%) 1	2 / 61 (3.28%) 2
Nausea subjects affected / exposed occurrences (all)	5 / 163 (3.07%) 5	6 / 126 (4.76%) 8	8 / 61 (13.11%) 10
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	2 / 126 (1.59%) 2	3 / 61 (4.92%) 3
Hepatobiliary disorders Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Skin and subcutaneous tissue disorders Eczema subjects affected / exposed occurrences (all)	4 / 163 (2.45%) 4	1 / 126 (0.79%) 2	3 / 61 (4.92%) 3
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	1 / 61 (1.64%) 1
Dry skin subjects affected / exposed occurrences (all)	3 / 163 (1.84%) 3	4 / 126 (3.17%) 4	5 / 61 (8.20%) 7
Alopecia subjects affected / exposed occurrences (all)	5 / 163 (3.07%) 5	1 / 126 (0.79%) 1	7 / 61 (11.48%) 7
Hair growth abnormal subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Henoch-Schonlein purpura subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	7 / 163 (4.29%) 9	3 / 126 (2.38%) 4	7 / 61 (11.48%) 8
Pruritus			

subjects affected / exposed occurrences (all)	2 / 163 (1.23%) 2	4 / 126 (3.17%) 4	4 / 61 (6.56%) 4
Nail disorder subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Scar pain subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Renal and urinary disorders Hypertonic bladder subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Urinary retention subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	1 / 126 (0.79%) 1	0 / 61 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	2 / 126 (1.59%) 2	1 / 61 (1.64%) 1
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	9 / 163 (5.52%) 10	43 / 126 (34.13%) 70	12 / 61 (19.67%) 18
Haematoma muscle subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	4 / 163 (2.45%) 4	10 / 126 (7.94%) 11	4 / 61 (6.56%) 4
Bursitis subjects affected / exposed occurrences (all)	0 / 163 (0.00%) 0	0 / 126 (0.00%) 0	0 / 61 (0.00%) 0
Arthritis subjects affected / exposed occurrences (all)	1 / 163 (0.61%) 1	6 / 126 (4.76%) 10	2 / 61 (3.28%) 2
Muscle spasms			

subjects affected / exposed	3 / 163 (1.84%)	2 / 126 (1.59%)	6 / 61 (9.84%)
occurrences (all)	3	3	7
Myalgia			
subjects affected / exposed	4 / 163 (2.45%)	22 / 126 (17.46%)	4 / 61 (6.56%)
occurrences (all)	5	27	4
Spinal stenosis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	11 / 163 (6.75%)	11 / 126 (8.73%)	9 / 61 (14.75%)
occurrences (all)	11	11	11
Rotator cuff syndrome			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	3 / 163 (1.84%)	6 / 126 (4.76%)	3 / 61 (4.92%)
occurrences (all)	3	9	3
Synovial cyst			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	2 / 163 (1.23%)	3 / 126 (2.38%)	0 / 61 (0.00%)
occurrences (all)	2	3	0
Tenosynovitis			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 163 (1.84%)	6 / 126 (4.76%)	0 / 61 (0.00%)
occurrences (all)	4	8	0
COVID-19			
subjects affected / exposed	0 / 163 (0.00%)	11 / 126 (8.73%)	4 / 61 (6.56%)
occurrences (all)	0	11	4
Cellulitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	2 / 61 (3.28%)
occurrences (all)	0	0	2

Dengue fever			
subjects affected / exposed	0 / 163 (0.00%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Helicobacter infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	1 / 163 (0.61%)	1 / 126 (0.79%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
Influenza			
subjects affected / exposed	2 / 163 (1.23%)	12 / 126 (9.52%)	5 / 61 (8.20%)
occurrences (all)	2	14	5
Oral candidiasis			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	10 / 163 (6.13%)	11 / 126 (8.73%)	10 / 61 (16.39%)
occurrences (all)	13	22	17
Localised infection			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 163 (0.61%)	7 / 126 (5.56%)	2 / 61 (3.28%)
occurrences (all)	1	7	2
Oral herpes			
subjects affected / exposed	0 / 163 (0.00%)	5 / 126 (3.97%)	1 / 61 (1.64%)
occurrences (all)	0	5	1
Periodontitis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	2 / 61 (3.28%)
occurrences (all)	0	0	2
Pharyngitis			
subjects affected / exposed	1 / 163 (0.61%)	3 / 126 (2.38%)	4 / 61 (6.56%)
occurrences (all)	1	7	5
Post viral fatigue syndrome			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Staphylococcal infection			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	3 / 163 (1.84%)	5 / 126 (3.97%)	3 / 61 (4.92%)
occurrences (all)	4	7	4
Rhinitis			
subjects affected / exposed	2 / 163 (1.23%)	1 / 126 (0.79%)	1 / 61 (1.64%)
occurrences (all)	2	1	1
Respiratory tract infection			
subjects affected / exposed	2 / 163 (1.23%)	5 / 126 (3.97%)	1 / 61 (1.64%)
occurrences (all)	2	6	1
Tooth infection			
subjects affected / exposed	1 / 163 (0.61%)	1 / 126 (0.79%)	4 / 61 (6.56%)
occurrences (all)	1	1	5
Upper respiratory tract infection			
subjects affected / exposed	7 / 163 (4.29%)	11 / 126 (8.73%)	6 / 61 (9.84%)
occurrences (all)	8	20	9
Wound infection			
subjects affected / exposed	1 / 163 (0.61%)	0 / 126 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
Urosepsis			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	4 / 163 (2.45%)	6 / 126 (4.76%)	5 / 61 (8.20%)
occurrences (all)	5	13	13
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 163 (0.00%)	2 / 126 (1.59%)	4 / 61 (6.56%)
occurrences (all)	0	2	6
Diabetes mellitus			
subjects affected / exposed	2 / 163 (1.23%)	2 / 126 (1.59%)	2 / 61 (3.28%)
occurrences (all)	2	2	2
Hypercholesterolaemia			

subjects affected / exposed	3 / 163 (1.84%)	3 / 126 (2.38%)	7 / 61 (11.48%)
occurrences (all)	3	3	7
Hyperglycaemia			
subjects affected / exposed	1 / 163 (0.61%)	5 / 126 (3.97%)	11 / 61 (18.03%)
occurrences (all)	1	8	18
Hypophosphataemia			
subjects affected / exposed	3 / 163 (1.84%)	1 / 126 (0.79%)	2 / 61 (3.28%)
occurrences (all)	3	3	7
Hypervolaemia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypoferritinaemia			
subjects affected / exposed	0 / 163 (0.00%)	0 / 126 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	1 / 163 (0.61%)	2 / 126 (1.59%)	6 / 61 (9.84%)
occurrences (all)	2	2	9
Iron deficiency			
subjects affected / exposed	2 / 163 (1.23%)	1 / 126 (0.79%)	1 / 61 (1.64%)
occurrences (all)	2	1	1

Non-serious adverse events	Nilotinib treatment continuation (NTCT) phase	Nilotinib treatment re-initiation-2 phase (NTRI-2)	Nilotinib treatment-free remission - 2 Phase (TRF-2)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 26 (73.08%)	2 / 2 (100.00%)	6 / 7 (85.71%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	4	0	1
Angiopathy			
subjects affected / exposed	0 / 26 (0.00%)	1 / 2 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Chest discomfort			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 26 (7.69%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Non-cardiac chest pain			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Menopausal symptoms			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Sinus disorder subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Depression subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Stress subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Blood cholesterol increased			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
Weight decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Arthropod sting subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Epicondylitis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Expired product administered subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Incision site haematoma subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Limb injury subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 2 (50.00%) 1	1 / 7 (14.29%) 2
Skin abrasion subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Tendon injury subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Cardiac disorders Angina pectoris subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Nervous system disorders			

Cognitive disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Carotid artery stenosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular stenosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	2 / 26 (7.69%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Facial paresis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gait spastic			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hemiplegia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Syncope subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Blood and lymphatic system disorders			
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Anaemia subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 2 (0.00%) 0	1 / 7 (14.29%) 2
Leukocytosis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Eye disorders			
Cataract subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Diarrhoea			

subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dental caries			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hypertransaminaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hair growth abnormal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Hypertonic bladder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 26 (7.69%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Haematoma muscle			

subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Arthritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Spinal stenosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Synovial cyst			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Tenosynovitis			

subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Cellulitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dengue fever			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Localised infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Periodontitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post viral fatigue syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 26 (0.00%)	1 / 2 (50.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 26 (3.85%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	7
Wound infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Urosepsis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 2 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Metabolism and nutrition disorders			
Dyslipidaemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	1 / 7 (14.29%) 1
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Hypercholesterolaemia subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	1 / 2 (50.00%) 1	1 / 7 (14.29%) 1
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Hypervolaemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 2 (50.00%) 1	0 / 7 (0.00%) 0
Hypoferritinaemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 2 (50.00%) 1	2 / 7 (28.57%) 2
Iron deficiency subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 2 (0.00%) 0	0 / 7 (0.00%) 0

Non-serious adverse events	Nilotinib treatment prolonged continuation phase (NTCT-P)	All patients	
Total subjects affected by non-serious adverse events subjects affected / exposed	11 / 14 (78.57%)	151 / 163 (92.64%)	

Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 14 (14.29%)	50 / 163 (30.67%)	
occurrences (all)	3	73	
Angiopathy			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	8 / 163 (4.91%)	
occurrences (all)	0	11	
Chest discomfort			
subjects affected / exposed	1 / 14 (7.14%)	5 / 163 (3.07%)	
occurrences (all)	1	5	
Cyst			
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)	
occurrences (all)	1	2	
Pain			
subjects affected / exposed	1 / 14 (7.14%)	6 / 163 (3.68%)	
occurrences (all)	1	7	
Oedema peripheral			
subjects affected / exposed	2 / 14 (14.29%)	17 / 163 (10.43%)	
occurrences (all)	3	22	
Non-cardiac chest pain			
subjects affected / exposed	2 / 14 (14.29%)	9 / 163 (5.52%)	
occurrences (all)	2	10	
Fatigue			
subjects affected / exposed	0 / 14 (0.00%)	19 / 163 (11.66%)	
occurrences (all)	0	23	
Pyrexia			
subjects affected / exposed	1 / 14 (7.14%)	10 / 163 (6.13%)	
occurrences (all)	1	11	
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	1 / 14 (7.14%)	5 / 163 (3.07%)	
occurrences (all)	1	9	

Menopausal symptoms subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	1 / 163 (0.61%) 1	
Menstruation irregular subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	1 / 163 (0.61%) 1	
Respiratory, thoracic and mediastinal disorders			
Nasal congestion subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	2 / 163 (1.23%) 2	
Dyspnoea subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	9 / 163 (5.52%) 16	
Cough subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 2	16 / 163 (9.82%) 22	
Oropharyngeal pain subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2	9 / 163 (5.52%) 10	
Sinus disorder subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	1 / 163 (0.61%) 1	
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	11 / 163 (6.75%) 11	
Depression subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	7 / 163 (4.29%) 7	
Insomnia subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	11 / 163 (6.75%) 14	
Stress subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 163 (0.61%) 1	
Investigations			

Alanine aminotransferase increased		
subjects affected / exposed	0 / 14 (0.00%)	13 / 163 (7.98%)
occurrences (all)	0	16
Aspartate aminotransferase increased		
subjects affected / exposed	0 / 14 (0.00%)	11 / 163 (6.75%)
occurrences (all)	0	15
Blood bilirubin increased		
subjects affected / exposed	0 / 14 (0.00%)	8 / 163 (4.91%)
occurrences (all)	0	13
Blood cholesterol increased		
subjects affected / exposed	2 / 14 (14.29%)	9 / 163 (5.52%)
occurrences (all)	2	9
Blood creatinine increased		
subjects affected / exposed	1 / 14 (7.14%)	11 / 163 (6.75%)
occurrences (all)	1	13
Blood potassium decreased		
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)
occurrences (all)	1	2
C-reactive protein increased		
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)
occurrences (all)	1	2
Cardiac murmur		
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)
occurrences (all)	1	2
Gamma-glutamyltransferase increased		
subjects affected / exposed	1 / 14 (7.14%)	5 / 163 (3.07%)
occurrences (all)	1	6
Lipase increased		
subjects affected / exposed	1 / 14 (7.14%)	12 / 163 (7.36%)
occurrences (all)	2	24
Serum ferritin decreased		
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)
occurrences (all)	1	2
Vitamin D decreased		

subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	2 / 163 (1.23%) 2	
Weight increased subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2	21 / 163 (12.88%) 24	
Weight decreased subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	12 / 163 (7.36%) 14	
Injury, poisoning and procedural complications			
Arthropod sting subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	2 / 163 (1.23%) 2	
Epicondylitis subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	5 / 163 (3.07%) 5	
Expired product administered subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2	4 / 163 (2.45%) 4	
Fall subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	9 / 163 (5.52%) 10	
Incision site haematoma subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	1 / 163 (0.61%) 1	
Limb injury subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	6 / 163 (3.68%) 7	
Procedural pain subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	5 / 163 (3.07%) 6	
Skin abrasion subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	2 / 163 (1.23%) 2	
Tendon injury			

subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	2 / 163 (1.23%) 2	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 14 (0.00%)	5 / 163 (3.07%)	
occurrences (all)	0	5	
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	9 / 163 (5.52%)	
occurrences (all)	0	10	
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)	
occurrences (all)	0	2	
Carotid artery stenosis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Cerebrovascular stenosis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Dizziness			
subjects affected / exposed	1 / 14 (7.14%)	15 / 163 (9.20%)	
occurrences (all)	1	18	
Dysaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences (all)	0	3	
Headache			
subjects affected / exposed	0 / 14 (0.00%)	25 / 163 (15.34%)	
occurrences (all)	0	32	
Facial paresis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Gait spastic			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Dysarthria			

subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Hemiparesis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Hemiplegia			
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)	
occurrences (all)	1	2	
Sciatica			
subjects affected / exposed	0 / 14 (0.00%)	9 / 163 (5.52%)	
occurrences (all)	0	10	
Syncope			
subjects affected / exposed	1 / 14 (7.14%)	4 / 163 (2.45%)	
occurrences (all)	1	4	
Paraesthesia			
subjects affected / exposed	1 / 14 (7.14%)	9 / 163 (5.52%)	
occurrences (all)	1	12	
Blood and lymphatic system disorders			
Increased tendency to bruise			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences (all)	0	1	
Anaemia			
subjects affected / exposed	2 / 14 (14.29%)	19 / 163 (11.66%)	
occurrences (all)	2	26	
Iron deficiency anaemia			
subjects affected / exposed	0 / 14 (0.00%)	6 / 163 (3.68%)	
occurrences (all)	0	15	
Leukocytosis			
subjects affected / exposed	1 / 14 (7.14%)	4 / 163 (2.45%)	
occurrences (all)	1	5	
Eye disorders			
Cataract			
subjects affected / exposed	1 / 14 (7.14%)	9 / 163 (5.52%)	
occurrences (all)	1	11	
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	2 / 14 (14.29%)	22 / 163 (13.50%)	
occurrences (all)	2	29	
Abdominal pain lower			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Abdominal pain upper			
subjects affected / exposed	2 / 14 (14.29%)	18 / 163 (11.04%)	
occurrences (all)	3	21	
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	9 / 163 (5.52%)	
occurrences (all)	0	11	
Diarrhoea			
subjects affected / exposed	1 / 14 (7.14%)	18 / 163 (11.04%)	
occurrences (all)	1	22	
Dental caries			
subjects affected / exposed	2 / 14 (14.29%)	4 / 163 (2.45%)	
occurrences (all)	2	4	
Constipation			
subjects affected / exposed	1 / 14 (7.14%)	21 / 163 (12.88%)	
occurrences (all)	1	24	
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	15 / 163 (9.20%)	
occurrences (all)	0	21	
Toothache			
subjects affected / exposed	1 / 14 (7.14%)	4 / 163 (2.45%)	
occurrences (all)	2	5	
Nausea			
subjects affected / exposed	2 / 14 (14.29%)	18 / 163 (11.04%)	
occurrences (all)	3	27	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 14 (7.14%)	7 / 163 (4.29%)	
occurrences (all)	1	7	
Hepatobiliary disorders			
Hypertransaminasaemia			

subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 163 (0.61%) 1	
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 14 (7.14%)	8 / 163 (4.91%)	
occurrences (all)	1	11	
Dermatitis acneiform			
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)	
occurrences (all)	1	2	
Dry skin			
subjects affected / exposed	0 / 14 (0.00%)	10 / 163 (6.13%)	
occurrences (all)	0	14	
Alopecia			
subjects affected / exposed	0 / 14 (0.00%)	12 / 163 (7.36%)	
occurrences (all)	0	13	
Hair growth abnormal			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences (all)	0	1	
Henoch-Schonlein purpura			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Rash			
subjects affected / exposed	1 / 14 (7.14%)	16 / 163 (9.82%)	
occurrences (all)	1	22	
Pruritus			
subjects affected / exposed	1 / 14 (7.14%)	11 / 163 (6.75%)	
occurrences (all)	1	11	
Nail disorder			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Scar pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Renal and urinary disorders			
Hypertonic bladder			

subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Urinary retention			
subjects affected / exposed	0 / 14 (0.00%)	3 / 163 (1.84%)	
occurrences (all)	0	3	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 14 (0.00%)	5 / 163 (3.07%)	
occurrences (all)	0	5	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 14 (7.14%)	62 / 163 (38.04%)	
occurrences (all)	1	101	
Haematoma muscle			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Back pain			
subjects affected / exposed	0 / 14 (0.00%)	17 / 163 (10.43%)	
occurrences (all)	0	19	
Bursitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences (all)	0	1	
Arthritis			
subjects affected / exposed	1 / 14 (7.14%)	10 / 163 (6.13%)	
occurrences (all)	1	14	
Muscle spasms			
subjects affected / exposed	2 / 14 (14.29%)	12 / 163 (7.36%)	
occurrences (all)	2	15	
Myalgia			
subjects affected / exposed	1 / 14 (7.14%)	32 / 163 (19.63%)	
occurrences (all)	1	39	
Spinal stenosis			
subjects affected / exposed	1 / 14 (7.14%)	2 / 163 (1.23%)	
occurrences (all)	1	2	
Pain in extremity			

subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2	29 / 163 (17.79%) 35	
Rotator cuff syndrome subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	1 / 163 (0.61%) 1	
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	11 / 163 (6.75%) 16	
Synovial cyst subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	2 / 163 (1.23%) 2	
Tendonitis subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	7 / 163 (4.29%) 8	
Tenosynovitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	2 / 163 (1.23%) 2	
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	9 / 163 (5.52%) 12	
COVID-19 subjects affected / exposed occurrences (all)	4 / 14 (28.57%) 5	20 / 163 (12.27%) 22	
Cellulitis subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2	4 / 163 (2.45%) 4	
Dengue fever subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	2 / 163 (1.23%) 2	
Helicobacter infection subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2	3 / 163 (1.84%) 3	
Ear infection subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	2 / 163 (1.23%) 3	

Influenza		
subjects affected / exposed	3 / 14 (21.43%)	20 / 163 (12.27%)
occurrences (all)	3	24
Oral candidiasis		
subjects affected / exposed	1 / 14 (7.14%)	3 / 163 (1.84%)
occurrences (all)	1	3
Nasopharyngitis		
subjects affected / exposed	2 / 14 (14.29%)	25 / 163 (15.34%)
occurrences (all)	3	56
Localised infection		
subjects affected / exposed	0 / 14 (0.00%)	2 / 163 (1.23%)
occurrences (all)	0	2
Pneumonia		
subjects affected / exposed	1 / 14 (7.14%)	11 / 163 (6.75%)
occurrences (all)	1	11
Oral herpes		
subjects affected / exposed	0 / 14 (0.00%)	7 / 163 (4.29%)
occurrences (all)	0	7
Periodontitis		
subjects affected / exposed	1 / 14 (7.14%)	3 / 163 (1.84%)
occurrences (all)	1	3
Pharyngitis		
subjects affected / exposed	0 / 14 (0.00%)	8 / 163 (4.91%)
occurrences (all)	0	13
Post viral fatigue syndrome		
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)
occurrences (all)	1	1
Staphylococcal infection		
subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)
occurrences (all)	0	1
Sinusitis		
subjects affected / exposed	1 / 14 (7.14%)	9 / 163 (5.52%)
occurrences (all)	1	16
Rhinitis		
subjects affected / exposed	2 / 14 (14.29%)	6 / 163 (3.68%)
occurrences (all)	2	6

Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	8 / 163 (4.91%) 10	
Tooth infection subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	7 / 163 (4.29%) 8	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 4	25 / 163 (15.34%) 49	
Wound infection subjects affected / exposed occurrences (all)	0 / 14 (0.00%) 0	3 / 163 (1.84%) 3	
Urosepsis subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	1 / 163 (0.61%) 1	
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 2	14 / 163 (8.59%) 33	
Metabolism and nutrition disorders			
Dyslipidaemia subjects affected / exposed occurrences (all)	2 / 14 (14.29%) 3	9 / 163 (5.52%) 12	
Diabetes mellitus subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	7 / 163 (4.29%) 7	
Hypercholesterolaemia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	14 / 163 (8.59%) 16	
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 2	18 / 163 (11.04%) 32	
Hypophosphataemia subjects affected / exposed occurrences (all)	1 / 14 (7.14%) 1	5 / 163 (3.07%) 14	
Hypervolaemia			

subjects affected / exposed	0 / 14 (0.00%)	1 / 163 (0.61%)	
occurrences (all)	0	1	
Hypoferritinaemia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 163 (0.61%)	
occurrences (all)	1	1	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 14 (7.14%)	10 / 163 (6.13%)	
occurrences (all)	2	18	
Iron deficiency			
subjects affected / exposed	1 / 14 (7.14%)	5 / 163 (3.07%)	
occurrences (all)	2	7	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 July 2013	<p>The main aim of this study protocol amendment was to enable patients to receive both clinical and commercial drug supplies, with all supplies remaining free and provided by Novartis. The amendment also implements several clarifications and updates based on queries raised during study startup. Key changes include: ensuring consistent pregnancy-related language across nilotinib trials and detailing actions if pregnancy occurs during treatment-free remission; extending the screening window from 14 to 28 days; clarifying imatinib treatment duration prior to switching to nilotinib; and outlining the screening and adverse event reporting process for patients transitioning from studies CAMN107A2405 (ENESTcmr) or CAMN107EIC01 (ENEST1st) to CAMN107A2408, in line with ICH E8 guidelines. This includes no expected new toxicities or carry-over effects and no need for a wash-out period. Other updates: earlier re-screening (window reduced to approx. 4 weeks \pm 7 days); continued monitoring of adverse events for 30 days post-treatment and SAE follow-up until resolution; clarified SAE causality reporting; added and clarified biomarker and optional pharmacogenetics sections; updated protocol title and moved certain content to correct sections; revised inclusion criteria for direct bilirubin; clarified TFR-2 and nilotinib continuation phases; allowed both manual and automated differential leucocyte counts; updated dose reduction guidance for non-haematologic toxicities; changed study duration units from years to weeks; clarified IRB/EC reporting responsibilities for early termination; and made minor editorial corrections.</p>

11 August 2014	<p>The main purposes for the amendment were:</p> <ul style="list-style-type: none"> • To include cholesterol testing in the assessment schedule. Elevations in total serum cholesterol and low density lipoprotein cholesterol have been observed very commonly (more than 10%) in patients treated with nilotinib and commonly (between 1 to 10%) in patients treated with imatinib. Most of the cholesterol elevations were Grade 1 (> ULN - 300 mg/dL; > ULN - 7.75 mmol/L) or 2 (> 300 - 400 mg/dL; > 7.75 - 10.34 mmol/L), and some elevations were present prior to initiation of CML therapy. Lipid profiles including total cholesterol, LDL-C and HDL-C will be assessed during the conduct of this study. If test results warrant intervention, investigators should follow their local standards of practice or treatment guidelines, which may recommend treatment even for grade 1 cholesterol elevation. Before prescribing a lipid lowering medication, the possibility of drug-drug interactions should be considered due to the moderate inhibitory effect of nilotinib on CYP3A4 isoenzyme that is involved in the metabolic pathway of some statins (HMG-CoA reductase inhibitors). Appendix Section 14.1.2 reflects these interactions and provides guidance. • To provide a harmonization on dose reductions guidelines across Novartis-sponsored Tassigna study protocols. Hence the dose reduction guidelines for the following nonhematologic toxicities have been updated: <ul style="list-style-type: none"> • Hepato-biliary • Cardiac QTc prolongation • Ischemic cardiovascular evaluation • Cardiac "other" • Pancreatitis • To incorporate guidance for the management of: <ul style="list-style-type: none"> • Serum cholesterol increases • Blood glucose increases • Other cardiac risk factors • Ischemic vascular or ischemic cardiovascular events occurring in patients treated with nilotinib. • To incorporate precaution of use for antacid drugs to be aligned with Tassigna® FDA Prescribing Information and EMA SmPC. <p>To define ischemic vascular and ischemic cardiovascular events as Adverse Events of special interest, and their reporting.</p>
01 April 2016	<p>The primary purpose for the amendment was:</p> <p>To include hepatitis B virus testing as one of the study procedures, to identify study patients who may be at risk of hepatitis B reactivation. Reactivation of hepatitis B virus can occur in patients who are chronic carriers of this virus and are receiving a drug of the BCR-ABL TKI class such as nilotinib. Some cases involving BCR-ABL TKI resulted in acute hepatic failure or fulminant hepatitis leading to liver transplantation or a fatal outcome</p>

15 November 2016	<p>The primary purpose for the amendment was:</p> <p>To extend the study duration to a minimum of 5 calendar years (264 weeks) after last patient entered the TFR phase and to include the corresponding analysis of data after nilotinib discontinuation, to confirm stability of the rate of patients staying in the TFR phase.</p> <p>To update and clarify additional analysis time points</p>
05 July 2018	<p>The primary purposes for the amendment were:</p> <p>To extend the study duration by a further period of 5 years to a minimum of 528 weeks (10 calendar years) after last patient entered the TFR phase in order to confirm stability of the rate of patients remaining in the TFR phase and to evaluate the long-term safety and potential risk of resistance to treatment after nilotinib discontinuation by collecting information on late relapses, loss of response and occurrence of mutations (risk of developing resistance)</p> <p>To evaluate the percentage of patients who are in stable response (MMR, MR4, and MR4.5) after achievement of that response in nilotinib re-initiation phase for 48 weeks, 96 weeks, 144 weeks, 192 weeks, 240 weeks, 288 weeks, 336 weeks, 384 weeks, and 432 weeks, based on availability of appropriate data.</p> <p>To update Section 6.4.3 prohibited concomitant therapy to bring clarity on action to be performed when QT prolonging drugs are taken depending on the risk category of Torsades de Pointe.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.nov> for complete trial results.

Notes: