Clinical trial results:
An open-label, multi-center, single-arm study to evaluate the efficacy of nilotinib in adult patients with metastatic or unresectable gastrointestinal stromal tumors in first line treatment

Summary

EudraCT number	2008-000358-11
Trial protocol	DE ES FI IT FR
Global end of trial date	18 December 2024

Results information

Result version number	v1 (current)
This version publication date	01 January 2026
First version publication date	01 January 2026

Trial information

Trial identification

Sponsor protocol code	CAMN107DDE06

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00756509
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 Pharma AG, 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	18 December 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 December 2024
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 efficacy of Nilotinib in participants with unresectable or metastatic gastrointestinal stromal tumors. Efficacy was defined as the proportion of patients showing stable disease (SD), partial response (PR) or complete response (CR) during the first 6 months, core phase, according to RECIST criteria.

Due to EudraCT system limitations, which EMA is aware of, data using 9999 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	26 August 2008
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	Finland: 5
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Italy: 9
Country: Number of subjects enrolled	Spain: 10
Worldwide total number of subjects	41
EEA total number of subjects	41

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)	28
From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study consists of participants with unresectable or metastatic gastrointestinal stromal tumors (GIST) showing progression of disease from 5 countries: Germany, Spain, Finland, France, Italy

Pre-assignment

Screening details:

All enrolled participants received 400 mg bid dose of nilotinib.

Period 1

Period 1 title	Core Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Nilotinib

Arm description:

Participants who received 400 mg bid of nilotinib

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

Dosage and administration details:

400 mg bid of nilotinib

Number of subjects in period 1	Nilotinib
Started	41
Completed	31
Not completed	10
Disease progression	6
Adverse event, non-fatal	2
Lack of efficacy	2

Period 2

Period 2 title	Follow-Up Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Nilotinib

Arm description:

Participants who received 400 mg bid of nilotinib

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

Dosage and administration details:

400 mg bid of nilotinib

Number of subjects in period 2	Nilotinib
Started	31
Completed	7
Not completed	24
Consent withdrawn by subject	1
Disease progression	9
Missing values	2
Adverse event, non-fatal	7
Administrative problems	3
Lost to follow-up	1
Subject's condition no longer requires study drug	1

Baseline characteristics

Reporting groups	
Reporting group title	Nilotinib
Reporting group description:	
Participants who received 400 mg bid of nilotinib	

Reporting group values	Nilotinib	Total	
Number of subjects	41	41	
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)	28	28	
From 65-84 years	13	13	
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	58		
standard deviation	± 10.4	-	
Sex: Female, Male Units: Participants			
Female	19	19	
Male	22	22	
Race/Ethnicity, Customized Units: Subjects			
Caucasian	40	40	
Black	1	1	

End points

End points reporting groups

Reporting group title	Nilotinib
Reporting group description: Participants who received 400 mg bid of nilotinib	
Reporting group title	Nilotinib
Reporting group description: Participants who received 400 mg bid of nilotinib	

Primary: Proportion of participants with Best Overall Response at month 6 (core phase) determined according to the RECIST v1.0.

End point title	Proportion of participants with Best Overall Response at month 6 (core phase) determined according to the RECIST v1.0.[1]

End point description:

The primary efficacy measure is the proportion of patients reaching Complete Response (CR), Partial Response (PR), or Stable Disease (SD) by Month 6, as per RECIST v1.0. Definitions are as follows: CR requires at least two CRs at least four weeks apart before any progression; PR requires two or more PRs at least four weeks apart, without qualifying for CR; SD is at least one SD more than six weeks after treatment start, not qualifying for CR or PR. Progressive Disease (PD) is defined as progression or cancer-related death within 12 weeks of starting treatment, not qualifying for CR, PR, or SD. UNK refers to cases not meeting these criteria, such as absence of confirmed CR/PR, no SD after six weeks, or early progression. The percentage of patients with CR, PR, or SD will be presented with a one-sided exact 90% (or 80% two-sided) confidence interval for the ITT_F group.

End point type	Primary

End point timeframe:

from baseline to month 6, core phase

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	Nilotinib			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Participants				
Complete Response (CR)	0			
Partial Response (PR)	14			
Stable Disease (SD)	21			
Progressive Disease (PD)	6			
Unknown (UNK)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with Objective Response Rate (ORR) at month 6 (core phase) observed according to RECIST

End point title	Proportion of participants with Objective Response Rate (ORR)

	at month 6 (core phase) observed according to RECIST

End point description:

Objective Response Rate (ORR) is defined as the proportion of patients in whom a complete (CR) or partial (PR) response was observed according to RECIST at month 6.

End point type	Secondary

End point timeframe:

from baseline to month 6, core phase

End point values	Nilotinib			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Percentage of responder				
number (confidence interval 80%)	34.1 (24.2 to 45.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival (PFS) for complete study (core and follow-up phases)

End point title	Progression-free survival (PFS) for complete study (core and follow-up phases)

End point description:

Progression-free survival (PFS) is defined as the time from first study drug administration to objective tumor progression or death from any cause. If a patient has not had an event, PFS is censored at the date of last adequate tumor assessment. PFS will be explored graphically by presenting the Kaplan-Meier curve.

End point type	Secondary

End point timeframe:

from date of first response (CR or PR) until progression or death, up to data cut off (up to approximately 16 years)

End point values	Nilotinib			
Subject group type	Reporting group			
Number of subjects analysed	31			
Units: Days				
median (confidence interval 95%)	2833 (791 to 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival for complete study (core and follow-up phases)

End point title	Overall Survival for complete study (core and follow-up phases)

End point description:

Overall Survival (OS) is defined as the time from first study drug administration to death from any cause. Participants alive at their last known follow-up were censored. No deaths occurred during the study.

End point type	Secondary

End point timeframe:

from date of first response (CR or PR) until progression or death, up to data cut off (up to approximately 16 years)

End point values	Nilotinib			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: Participants				

Notes:

[2] - No deaths occurred, so no participants were included in the survival analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with treatment-emergent adverse events during the entire study (core and follow-up phases)

End point title	Proportion of participants with treatment-emergent adverse events during the entire study (core and follow-up phases)

End point description:

This measure summarizes the proportion of participants who experienced at least one treatment-emergent adverse event (TEAE) during the entire study period, including both core and follow-up phases. A TEAE was defined as an adverse event that began or worsened after the first dose of study treatment.

End point type	Secondary

End point timeframe:

from the first dose through the end of the study (core and follow-up phases): including all visits up to the follow-up database lock (approximately 16 years)

End point values	Nilotinib			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Participants				
All AEs	39			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response (TTR) at Month 6 (core phase)

End point title	Time to Response (TTR) at Month 6 (core phase)

End point description:

Time to response is defined as the time from start of treatment to the first objective tumor response (PR or CR) observed. Patients who did not achieve a confirmed PR or CR will be censored at last adequate tumor assessment date when they did not progress (including deaths not due to underlying disease).

End point type	Secondary

End point timeframe:

from baseline to month 6, core phase

End point values	Nilotinib			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: Days				
median (confidence interval 95%)	62 (57 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response (CR or PR) for complete study (core and follow-up phases)

End point title	Duration of response (CR or PR) for complete study (core and follow-up phases)

End point description:

Duration of response is defined as the time from onset of response (CR/PR) to objective tumor progression or death from any cause. Patients not experiencing progression or death will be censored with the date of their last adequate tumor assessment.

End point type	Secondary

End point timeframe:

from date of first response (CR or PR) until progression or death, up to data cut off (up to approximately 16 years)

End point values	Nilotinib			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: Days				
median (confidence interval 95%)	2722 (588 to 9999)			

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 through the end of the study (core and follow-up phases), including all visits up to the follow-up database lock (approximately 16 years).

Adverse event reporting additional description:

Any signs or symptoms were collected from first dose through the end of the study (core and follow-up phases), including all visits up to the follow-up database lock (approximately 16 years).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	Total Follow up

Reporting group description:

Total Follow up Phase

Reporting group title	Total Core

Reporting group description:

Total Core Phase

Serious adverse events	Total Follow up	Total Core	
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 31 (45.16%)	10 / 41 (24.39%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR RUPTURE			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
KERATOACANTHOMA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLASMA CELL MYELOMA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Vascular disorders			
ARTERIAL THROMBOSIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CIRCULATORY COLLAPSE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ARTERIAL OCCLUSIVE DISEASE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 10	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
PYREXIA			
subjects affected / exposed	2 / 31 (6.45%)	2 / 41 (4.88%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHEST PAIN			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR STENT STENOSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERPLASIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERAL PHYSICAL HEALTH DETERIORATION			

subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
MULTIPLE SCLEROSIS RELAPSE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
PULMONARY HYPERTENSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
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			
ARTERIAL RESTENOSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
MYOCARDIAL INFARCTION			

subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE CHRONIC			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERICARDIAL EFFUSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ARTERY DISEASE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
NEURITIS			

subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEADACHE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAROTID ARTERY STENOSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
VESTIBULAR DISORDER			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VERTIGO			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
GLAUCOMA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OCULAR HYPERTENSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
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	2 / 31 (6.45%)	2 / 41 (4.88%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBILEUS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
TOXIC NODULAR GOITRE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
SEPSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STREPTOCOCCAL SEPSIS			

subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
HYPERCALCAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
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: 2 %

Non-serious adverse events	Total Follow up	Total Core	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 31 (90.32%)	39 / 41 (95.12%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
SKIN PAPILLOMA			
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)	
occurrences (all)	2	1	
SPINAL HAEMANGIOMA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
BASAL CELL CARCINOMA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HAEMANGIOMA OF BONE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PAPILLOMA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
ARTERIOSCLEROSIS			
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)	
occurrences (all)	2	1	
HOT FLUSH			

subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	1	2	
HYPERTENSION			
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)	
occurrences (all)	2	1	
PERIPHERAL COLDNESS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PERIPHERAL ARTERIAL OCCLUSIVE DISEASE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	3	0	
INTERMITTENT CLAUDICATION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
HYPERTENSIVE CRISIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
AORTIC ANEURYSM			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
VENOUS THROMBOSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
ANEURYSM			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
VITRECTOMY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
GASTROOESOPHAGEAL REFLUX PROPHYLAXIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
ASTRINGENT THERAPY			

subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
PYREXIA			
subjects affected / exposed	3 / 31 (9.68%)	2 / 41 (4.88%)	
occurrences (all)	10	4	
ASTHENIA			
subjects affected / exposed	2 / 31 (6.45%)	11 / 41 (26.83%)	
occurrences (all)	3	11	
CHEST DISCOMFORT			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
CHEST PAIN			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	2	
FACE OEDEMA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
FATIGUE			
subjects affected / exposed	5 / 31 (16.13%)	10 / 41 (24.39%)	
occurrences (all)	9	12	
FEELING COLD			
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	2	2	
LOCAL SWELLING			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
OEDEMA			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
OEDEMA PERIPHERAL			

subjects affected / exposed	7 / 31 (22.58%)	8 / 41 (19.51%)	
occurrences (all)	17	10	
THIRST			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
INFLAMMATION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
INFUSION SITE EXTRAVASATION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
MALAISE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PSEUDOCYST			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
MULTIPLE SCLEROSIS RELAPSE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
MULTIPLE SCLEROSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
ERECTILE DYSFUNCTION			
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	1	2	
NIPPLE OEDEMA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
NIPPLE PAIN			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
PELVIC PAIN			

subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
TESTIS DISCOMFORT			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
DYSPNOEA			
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	3	2	
COUGH			
subjects affected / exposed	3 / 31 (9.68%)	2 / 41 (4.88%)	
occurrences (all)	4	2	
DYSPHONIA			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	3	
PLEURAL EFFUSION			
subjects affected / exposed	3 / 31 (9.68%)	1 / 41 (2.44%)	
occurrences (all)	3	1	
THROAT IRRITATION			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	2	
SLEEP APNOEA SYNDROME			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PLEURITIC PAIN			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HIATUS HERNIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
EMPHYSEMA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
CATARRH			

subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	1	2	
ILLUSION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
NERVOUSNESS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
RESTLESSNESS			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
SLEEP DISORDER			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
INSOMNIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
ANXIETY DISORDER			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PANIC ATTACK			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
MOOD SWINGS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
CONFUSIONAL STATE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	3 / 31 (9.68%)	2 / 41 (4.88%)	
occurrences (all)	4	3	
BLOOD AMYLASE INCREASED			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	1	2	
LIPASE INCREASED			
subjects affected / exposed	3 / 31 (9.68%)	1 / 41 (2.44%)	
occurrences (all)	5	1	
TRANSAMINASES INCREASED			
subjects affected / exposed	2 / 31 (6.45%)	5 / 41 (12.20%)	
occurrences (all)	2	6	
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)	
occurrences (all)	4	1	
CARDIAC MURMUR			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
AMYLASE INCREASED			

subjects affected / exposed	3 / 31 (9.68%)	0 / 41 (0.00%)	
occurrences (all)	3	0	
COLONOSCOPY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
INTRAOCULAR PRESSURE INCREASED			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
CONTUSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
FRACTURE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
JOINT DISLOCATION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
WOUND			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
THORACIC VERTEBRAL FRACTURE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
SPLINTER			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
SKIN ABRASION			

subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
RIB FRACTURE			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	3	0	
Cardiac disorders			
PALPITATIONS			
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	1	2	
ANGINA PECTORIS			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
CORONARY ARTERY DISEASE			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PERICARDIAL EFFUSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	3 / 31 (9.68%)	2 / 41 (4.88%)	
occurrences (all)	3	2	
DYSGEUSIA			
subjects affected / exposed	2 / 31 (6.45%)	4 / 41 (9.76%)	
occurrences (all)	2	4	
HEADACHE			
subjects affected / exposed	5 / 31 (16.13%)	11 / 41 (26.83%)	
occurrences (all)	7	11	
MEMORY IMPAIRMENT			

subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
PARAESTHESIA			
subjects affected / exposed	5 / 31 (16.13%)	1 / 41 (2.44%)	
occurrences (all)	7	1	
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	2 / 31 (6.45%)	2 / 41 (4.88%)	
occurrences (all)	4	2	
CAROTID ARTERY STENOSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
CEREBROVASCULAR DISORDER			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
DECREASED VIBRATORY SENSE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
DISTURBANCE IN ATTENTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HYPOAESTHESIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
NYSTAGMUS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PARESIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PARTIAL SEIZURES			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
POLYNEUROPATHY			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
VASCULAR DEMENTIA			

subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	4 / 31 (12.90%)	2 / 41 (4.88%)	
occurrences (all)	4	2	
NEUTROPENIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
AGRANULOCYTOSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
SPLENIC INFARCTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
HYPOACUSIS			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
EAR SWELLING			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
EXTERNAL EAR INFLAMMATION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
TINNITUS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
VERTIGO			
subjects affected / exposed	5 / 31 (16.13%)	0 / 41 (0.00%)	
occurrences (all)	7	0	
Eye disorders			
OCULAR HYPERAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
ABNORMAL SENSATION IN EYE			

subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
DRY EYE			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	3	2	
EYELID PAIN			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
EYE PAIN			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
GLAUCOMA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
OCULAR HYPERTENSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PERIORBITAL OEDEMA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	8 / 31 (25.81%)	11 / 41 (26.83%)	
occurrences (all)	11	15	
ABDOMINAL PAIN LOWER			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 31 (0.00%)	4 / 41 (9.76%)	
occurrences (all)	0	4	
CONSTIPATION			
subjects affected / exposed	9 / 31 (29.03%)	7 / 41 (17.07%)	
occurrences (all)	13	8	

GASTRITIS EROSIVE				
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)		
occurrences (all)	0	1		
DYSPEPSIA				
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)		
occurrences (all)	3	1		
DYSPHAGIA				
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)		
occurrences (all)	0	1		
FLATULENCE				
subjects affected / exposed	2 / 31 (6.45%)	4 / 41 (9.76%)		
occurrences (all)	2	5		
GASTRIC POLYPS				
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)		
occurrences (all)	1	1		
DIARRHOEA				
subjects affected / exposed	3 / 31 (9.68%)	8 / 41 (19.51%)		
occurrences (all)	9	11		
GASTROOESOPHAGEAL REFLUX DISEASE				
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)		
occurrences (all)	1	2		
HIATUS HERNIA				
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)		
occurrences (all)	1	1		
NAUSEA				
subjects affected / exposed	5 / 31 (16.13%)	8 / 41 (19.51%)		
occurrences (all)	8	8		
TOOTHACHE				
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)		
occurrences (all)	2	1		
VOMITING				
subjects affected / exposed	4 / 31 (12.90%)	4 / 41 (9.76%)		
occurrences (all)	11	4		
HAEMORRHOIDS				

subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
GASTRITIS HAEMORRHAGIC			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
DRY MOUTH			
subjects affected / exposed	3 / 31 (9.68%)	0 / 41 (0.00%)	
occurrences (all)	4	0	
DIVERTICULUM INTESTINAL			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
ASCITES			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
AEROPHAGIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL DISCOMFORT			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	7	0	
GINGIVAL RECESSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HAEMATOCHEZIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
LIP ULCERATION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
REFLUX GASTRITIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			

HEPATOTOXICITY			
subjects affected / exposed	1 / 31 (3.23%)	3 / 41 (7.32%)	
occurrences (all)	1	3	
HYPERBILIRUBINAEMIA			
subjects affected / exposed	4 / 31 (12.90%)	6 / 41 (14.63%)	
occurrences (all)	4	7	
HYPERTRANSAMINASAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
HEPATITIS TOXIC			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
CHOLELITHIASIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HEPATIC PAIN			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	9 / 31 (29.03%)	8 / 41 (19.51%)	
occurrences (all)	9	8	
DRY SKIN			
subjects affected / exposed	8 / 31 (25.81%)	8 / 41 (19.51%)	
occurrences (all)	11	11	
ECZEMA			
subjects affected / exposed	1 / 31 (3.23%)	3 / 41 (7.32%)	
occurrences (all)	1	4	
ERYTHEMA			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
HYPERHIDROSIS			
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	1	2	
NIGHT SWEATS			

subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)		
occurrences (all)	3	1		
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME				
subjects affected / exposed	2 / 31 (6.45%)	2 / 41 (4.88%)		
occurrences (all)	2	2		
PETECHIAE				
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)		
occurrences (all)	1	1		
PHOTOSENSITIVITY REACTION				
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)		
occurrences (all)	2	1		
PILOERECTION				
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)		
occurrences (all)	0	1		
PRURITUS				
subjects affected / exposed	5 / 31 (16.13%)	11 / 41 (26.83%)		
occurrences (all)	7	12		
RASH				
subjects affected / exposed	6 / 31 (19.35%)	10 / 41 (24.39%)		
occurrences (all)	7	14		
XANTHELASMA				
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)		
occurrences (all)	1	1		
ONYCHOCLASIS				
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)		
occurrences (all)	1	0		
NAIL DISORDER				
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)		
occurrences (all)	1	0		
HAIR COLOUR CHANGES				
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)		
occurrences (all)	1	0		
EYELID INFECTION				
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)		
occurrences (all)	1	0		

STASIS DERMATITIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
SCAR PAIN			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
Renal and urinary disorders			
HAEMATURIA			
subjects affected / exposed	0 / 31 (0.00%)	2 / 41 (4.88%)	
occurrences (all)	0	2	
NOCTURIA			
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)	
occurrences (all)	3	1	
POLLAKIURIA			
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	1	2	
RENAL FAILURE			
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)	
occurrences (all)	2	1	
CALCULUS URINARY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
BLADDER DISCOMFORT			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
CHRONIC KIDNEY DISEASE			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
URINARY RETENTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
DYSURIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			

GOITRE			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
HYPERTHYROIDISM			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
Musculoskeletal and connective tissue disorders			
FLANK PAIN			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
ARTHRALGIA			
subjects affected / exposed	4 / 31 (12.90%)	8 / 41 (19.51%)	
occurrences (all)	5	8	
BACK PAIN			
subjects affected / exposed	5 / 31 (16.13%)	5 / 41 (12.20%)	
occurrences (all)	7	5	
BONE PAIN			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
GROIN PAIN			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
MUSCLE SPASMS			
subjects affected / exposed	5 / 31 (16.13%)	5 / 41 (12.20%)	
occurrences (all)	5	6	
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
MYALGIA			
subjects affected / exposed	3 / 31 (9.68%)	2 / 41 (4.88%)	
occurrences (all)	3	2	
NECK PAIN			

subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
PAIN IN EXTREMITY			
subjects affected / exposed	4 / 31 (12.90%)	5 / 41 (12.20%)	
occurrences (all)	8	5	
JOINT SWELLING			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
MUSCULAR WEAKNESS			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
OSTEOCHONDROSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
OSTEOARTHRITIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
OSTEOLYSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
CYSTITIS			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
EAR INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
FEBRILE INFECTION			

subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
GASTROENTERITIS			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
HERPES ZOSTER			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
NASOPHARYNGITIS			
subjects affected / exposed	6 / 31 (19.35%)	8 / 41 (19.51%)	
occurrences (all)	18	10	
ORAL HERPES			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
TOOTH ABSCESS			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
TOOTH INFECTION			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
VIRAL INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
FOLLICULITIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
EYE INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
CORONAVIRUS INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
CONJUNCTIVITIS			

subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
BRONCHITIS			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
GANGRENE			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
SINUSITIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
PNEUMONIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
PERIODONTITIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
ONYCHOMYCOSIS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
LOCALISED INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HERPES SIMPLEX			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
GASTROINTESTINAL INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
SKIN INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	

URINARY TRACT INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
WOUND INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 31 (0.00%)	5 / 41 (12.20%)	
occurrences (all)	0	5	
HYPERCALCAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	2 / 41 (4.88%)	
occurrences (all)	1	2	
HYPERKALAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
HYPERLIPASAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	1 / 41 (2.44%)	
occurrences (all)	1	1	
HYPERURICAEMIA			
subjects affected / exposed	0 / 31 (0.00%)	1 / 41 (2.44%)	
occurrences (all)	0	1	
HYPOPHOSPHATAEMIA			
subjects affected / exposed	2 / 31 (6.45%)	1 / 41 (2.44%)	
occurrences (all)	4	1	
TYPE 2 DIABETES MELLITUS			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
VITAMIN D DEFICIENCY			

subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
DIABETES MELLITUS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
FOLATE DEFICIENCY			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
GOUT			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HYPERAMYLASAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HYPERNATRAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
HYPERPROTEINAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 31 (3.23%)	0 / 41 (0.00%)	
occurrences (all)	1	0	
HYPONATRAEMIA			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	
IRON DEFICIENCY			
subjects affected / exposed	2 / 31 (6.45%)	0 / 41 (0.00%)	
occurrences (all)	2	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 October 2008	Amendment 1: The rational for this amendment was to allow patients who recently started their treatment with Imatinib to enter this trial. A transfer from other centers to the study centers was manageable without leaving the patient untreated. Often patients were treated in this stage of the disease in centers where no clinical trials can be offered. This amendment allowed these patients to be treated also in clinical trials and alleviated the recruitment
01 September 2009	Amendment 2: With this amendment the follow up period was extended. Patients were treated and followed until tumor progression. The visits were done 3 monthly.
10 June 2011	Amendment 3: This protocol amendment included the opportunity for patients to discontinue the study prematurely to receive the standard treatment imatinib for gastrointestinal stromal tumors (GIST). The decision for protocol amendment was performed in accordance to a Novartis decision taken on May 5, 2011 to discontinue the ongoing clinical trials with nilotinib in GIST.
06 January 2014	Amendment 4: Novartis took the decision to discontinue the ongoing clinical trials with nilotinib in GIST (CAMN107G2301 and CAMN107DDE05). The enrollment of this study (CAMN107DDE06) was re-opened in order to ensure continued access to nilotinib to the patients of the trials CAMN107G2301 trial and CAMN107DDE05 in Germany.
26 November 2018	Amendment 5: The primary purposes of the amendment are: To remove the pharmacokinetic analysis from the protocol. The pharmacokinetic of nilotinib have been explored very well in human and new results are not expected from further analysis of pharmacokinetic samples. To reduce the burden to the patients, the visit schedule will be adapted to every 6 month. Additionally visits between the 6-month-period are at the discretion of the investigator and/or local physician and will be done as a local routine

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 9999 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: