



Clinical trial results:

STI571 Prospective International Randomised Trial 2 - A phase III, prospective randomised comparison of imatinib (STI571, Glivec/Gleevec) 400mg daily versus dasatinib (Sprycel) 100mg daily in patients with newly-diagnosed chronic phase chronic myeloid leukaemia.

Summary

EudraCT number	2007-006185-15
Trial protocol	GB
Global end of trial date	07 March 2018

Results information

Result version number	v1 (current)
This version publication date	08 June 2019
First version publication date	08 June 2019

Trial information

Trial identification

Sponsor protocol code	SPIRIT 2
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Additional study identifiers

ISRCTN number	ISRCTN54923521
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Newcastle-upon-Tyne Hospitals NHS Foundation Trust
Sponsor organisation address	Level 1, Regent Point, Regent Farm Road, Newcastle upon Tyne, United Kingdom, NE3 3HD
Public contact	Professor Stephen O'Brien, Newcastle Clinical Trials Unit, 0044 0191 208 2522, stephen.o'brien@ncl.ac.uk
Scientific contact	Professor Stephen O'Brien, Newcastle Clinical Trials Unit, 0044 0191 208 2522, stephen.o'brien@ncl.ac.uk

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	21 May 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 March 2018
Global end of trial reached?	Yes
Global end of trial date	07 March 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare 5-year Event Free Survival (EFS) between the two treatment arms. The study is powered to demonstrate superiority of the dasatinib arm over the imatinib arm.

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:

none

Evidence for comparator: -

Actual start date of recruitment	07 August 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 814
Worldwide total number of subjects	814
EEA total number of subjects	814

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)	618
From 65 to 84 years	189
85 years and over	7

Subject disposition

Recruitment

Recruitment details:

Patients were recruited from haematology clinics in UK hospitals from August 2007 until end of February 2013. Eligible patients were screened by haematology consultants and then written informed consent obtained.

Pre-assignment

Screening details:

Patients had blood tests (haematology and biochemistry), a bone marrow sample (aspirate and trephine) taken and a physical examination performed. Medical history and details of any concomitant diseases and any treatment given post diagnosis was noted. If patient met inclusion criteria and none of the exclusion criteria, they were then randomised.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A

Arm description:

Imatinib 400mg per day

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

Dosage and administration details:

One 400mg tablet to be taken orally each day with water.

Arm title	Arm B
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Arm description:

Dasatinib 100mg daily

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

Dosage and administration details:

One 100mg tablet to be taken once a day, orally, with water.

Number of subjects in period 1^[1]	Arm A	Arm B
Started	406	406
Completed	194	230
Not completed	212	176
Consent withdrawn by subject	2	1
Adverse event, non-fatal	68	123
Pregnancy	2	4
Patient did not want to continue first line drug	8	8
patient developed another concomitant condition	4	-
joined another clinical trial	-	1
developed a concomitant condition	-	8
Lost to follow-up	4	3
Lack of efficacy	49	20
Inadequate PCR response/loss of PCR response	67	6
patient joined another clinical trial	7	-
Protocol deviation	1	2

Notes:

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

Justification: Only 812 (406 in each arm), out of 814 recruited, received treatment. So all study results are based on FAS/SAF analysis population, which consists actually on 812 total patients.

Baseline characteristics

Reporting groups

Reporting group title	Arm A
Reporting group description: Imatinib 400mg per day	
Reporting group title	Arm B
Reporting group description: Dasatinib 100mg daily	

Reporting group values	Arm A	Arm B	Total
Number of subjects	406	406	812
Age categorical			
Units: Subjects			
Adults (18-64 years)	309	308	617
From 65-84 years	96	92	188
85 years and over	1	6	7
Age continuous			
Units: years			
arithmetic mean	53.3	53.1	
standard deviation	± 14.7	± 15.4	-
Gender categorical			
Male and female patients were selected from haematology clinics across the UK			
Units: Subjects			
Female	165	155	320
Male	241	251	492
Sokal Score			
prognostic indicator at baseline			
Good prognosis (<0.8)			
Moderate prognosis (0.8-1.2)			
Poor prognosis (>1.2)			
Units: Subjects			
Good prognosis	80	94	174
Moderate prognosis	86	78	164
Poor prognosis	52	55	107
not recorded	188	179	367
Hasford Score			
prognostic indicator measured at baseline			
Low risk (equal to or less than score of 780)			
Intermediate risk (>780 to less than or equal to 1480)			
High risk (>1480)			
Units: Subjects			
Low risk	83	84	167
Intermediate risk	99	107	206
high risk	23	17	40
not recorded	201	198	399
EUTOS Score			
Prognostic score calculated at baseline			
Low risk (less than or equal to 87)			
High risk (>87)			
Units: Subjects			

Low risk	269	255	524
High risk	52	46	98
Not recorded	85	105	190
ELTS Score			
EUTOS long term survival score. Prognostics score calculated at baseline Low risk (less than or equal to 1.5680) Intermediate risk (>1.5680 to less than or equal to 2.2185) High risk (>2.2185)			
Units: Subjects			
Low risk	122	133	255
Intermediate risk	62	67	129
High risk	34	27	61
Not recorded	188	179	367
BCR-ABL transcript type			
breakpoint recorded at baseline from PCR sample			
Units: Subjects			
E13A2	142	146	288
E14A2	197	187	384
E13A2+E14A2	60	61	121
E1A2	1	2	3
not recorded	6	10	16
Time since CML diagnosis			
number of days between diagnosis and start of treatment			
Units: days			
arithmetic mean	15	16	
full range (min-max)	0 to 94	0 to 91	-

Subject analysis sets

Subject analysis set title	FAS
Subject analysis set type	Full analysis

Subject analysis set description:

The FAS is defined as all randomised patients who received study medication at least once. Patients will be analysed according to the treatment group to which they were randomised, rather than by the actual treatment they were administered. The FAS is the primary population of interest for all efficacy analyses.

Subject analysis set title	Safety Set
Subject analysis set type	Safety analysis

Subject analysis set description:

All patients who are randomised into the study and who received study medication at least once will be considered evaluable for the Safety Set. This is the same definition as the FAS. However, in the event that a patient receives study medication other than that to which they have been randomised, analyses based on the Safety Set will be performed using the actual treatment group that was administered and so will be different to the FAS. All safety tables will be based on the Safety Set.

Reporting group values	FAS	Safety Set	
Number of subjects	812	812	
Age categorical			
Units: Subjects			
Adults (18-64 years)	617	617	
From 65-84 years	188	188	
85 years and over	7	7	

Age continuous Units: years arithmetic mean standard deviation	53.2 ± 15.0	53.2 ± 15.0	
Gender categorical			
Male and female patients were selected from haematology clinics across the UK			
Units: Subjects			
Female	320	320	
Male	492	492	
Sokal Score			
prognostic indicator at baseline Good prognosis (<0.8) Moderate prognosis (0.8-1.2) Poor prognosis (>1.2)			
Units: Subjects			
Good prognosis			
Moderate prognosis			
Poor prognosis			
not recorded			
Hasford Score			
prognostic indicator measured at baseline Low risk (equal to or less than score of 780) Intermediate risk (>780 to less than or equal to 1480) High risk (>1480)			
Units: Subjects			
Low risk			
Intermediate risk			
high risk			
not recorded			
EUTOS Score			
Prognostic score calculated at baseline Low risk (less than or equal to 87) High risk (>87)			
Units: Subjects			
Low risk			
High risk			
Not recorded			
ELTS Score			
EUTOS long term survival score. Prognostics score calculated at baseline Low risk (less than or equal to 1.5680) Intermediate risk (>1.5680 to less than or equal to 2.2185) High risk (>2.2185)			
Units: Subjects			
Low risk			
Intermediate risk			
High risk			
Not recorded			
BCR-ABL transcript type			
breakpoint recorded at baseline from PCR sample			
Units: Subjects			
E13A2			
E14A2			
E13A2+E14A2			
E1A2			
not recorded			

Time since CML diagnosis			
number of days between diagnosis and start of treatment			
Units: days			
arithmetic mean			
full range (min-max)			

End points

End points reporting groups

Reporting group title	Arm A
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Reporting group description:

Imatinib 400mg per day

Reporting group title	Arm B
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Reporting group description:

Dasatinib 100mg daily

Subject analysis set title	FAS
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Subject analysis set type	Full analysis
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Subject analysis set description:

The FAS is defined as all randomised patients who received study medication at least once. Patients will be analysed according to the treatment group to which they were randomised, rather than by the actual treatment they were administered. The FAS is the primary population of interest for all efficacy analyses.

Subject analysis set title	Safety Set
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Subject analysis set type	Safety analysis
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Subject analysis set description:

All patients who are randomised into the study and who received study medication at least once will be considered evaluable for the Safety Set. This is the same definition as the FAS. However, in the event that a patient receives study medication other than that to which they have been randomised, analyses based on the Safety Set will be performed using the actual treatment group that was administered and so will be different to the FAS. All safety tables will be based on the Safety Set.

Primary: Event free survival at 5 years

End point title	Event free survival at 5 years
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End point description:

To establish whether dasatinib is superior to imatinib in terms of event free survival censored at 5 years. An event includes death from any cause, disease progression, loss of complete haematological response (CHR), increasing white blood cell count, or loss of major cytogenetic response (MCR).

End point type	Primary
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End point timeframe:

5 years

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	406	406		
Units: number of patients				
Death: non CML related	23	21		
Death: CML related	2	0		
Disease progression - blast crisis	7	6		
disease progression - accelerated phase	4	4		
Loss of CHR	5	3		
Loss of MCR	2	1		
Increasing white blood cell count	0	0		
No event	363	371		

Attachments (see zip file)	Kaplan-Meier Plot of Event Free Survival/KM_Overall.png
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Statistical analyses

Statistical analysis title	Event-Free Survival Kaplan-Meier Analysis
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Statistical analysis description:

An event includes: death (any cause), disease progression, loss of CHR, increase in WBC count, or loss of MCR. See protocol for full details.

Event-free survival is calculated as (Date of event - Date of first dose of study medication)/30.4.

Patients who have not experienced an event within 5 years are censored at the earliest of (date of last visit, or the date of first dose of study medication + 1826.25 days).

Comparison groups	Arm B v Arm A
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.318
Method	Logrank

Statistical analysis title	Event-Free Survival Cox Proportional Hazard Model
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Statistical analysis description:

An event includes: death (any cause), disease progression, loss of CHR, increase in WBC count, or loss of MCR. See protocol for full details.

Event-free survival is calculated as (Date of event - Date of first dose of study medication)/30.4.

Patients who have not experienced an event within 5 years are censored at the earliest of (Date of last visit, or the date of first dose of study medication + 1826.25 days).

Comparison groups	Arm B v Arm A
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	superiority ^[1]
P-value	= 0.319
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.797
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.245

Notes:

[1] - Analysis is based on a Cox proportional hazards model with treatment group included as an explanatory variable.

Statistical analysis title	Sensitivity Analysis
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Statistical analysis description:

Event-Free Survival Cox Proportional Hazards Model (Sensitivity Analysis)

An event includes: death (any cause), disease progression, loss of CHR, increase in WBC count, or loss of MCR. See protocol for full details.

Event-free survival is calculated as (Date of event - Date of first dose of study medication)/30.4.

Patients who have not experienced an event within 5 years are censored at the earliest of (Date of last visit, or the date of first dose of study medication + 1826.25 days).

Comparison groups	Arm B v Arm A
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	superiority ^[2]
P-value	= 0.216
Method	Regression, Cox
Parameter estimate	Cox proportional hazard
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.476
upper limit	1.183

Notes:

[2] - Analysis is based on a Cox proportional hazards model with treatment group, gender, BCR-ABL transcript, dose received in first 3 months (<90% or =90%) included as explanatory variables.

Secondary: Rate of complete cytogenetic response

End point title	Rate of complete cytogenetic response
End point description:	
The proportion of patients achieving CCR according to the G banding . For G-banding: CCR is defined as 0% Philadelphia chromosome positive metaphases in bone marrow cells. Data is presented as observed and worst case data where worst case presumes patients with missing cytogenetic responses are non-responders. Worst case data is presented as attachment.	
End point type	Secondary
End point timeframe:	
24 months	

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	406	406		
Units: number of patients				
Yes	129	173		
No	28	27		
not evaluable	249	206		

Attachments (see zip file)	Complete cytogenetic response by G-banding - worst case
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Statistical analyses

Statistical analysis title	Complete Cytogenetic Response(CCR) (Observed Data)
Comparison groups	Arm B v Arm A
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26
Method	Chi-squared

Secondary: Rate of treatment failure

End point title	Rate of treatment failure
End point description:	
Treatment failure includes all events, intolerance (such that the patient has to stop study drug permanently) , failure to achieve complete haematological response (CHR) after 6 months of treatment, failure to achieve major cytogenetic response (MCR) after 12 months of treatment, failure to achieve CCR after 24 months of treatment, failure to achieve adequate PCR (defined as >10% after 3 months treatment, >1% after 6 months treatment and >0/1% after 12 months treatment) and loss of adequate PCR response (as assessed by investigator).	
End point type	Secondary
End point timeframe:	
5 years	

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	406	406		
Units: Number of patients				
Death: non CML related	14	12		
Death: CML related	0	0		
Disease progression - blast crisis	7	4		
Disease progression - accelerated phase	0	4		
Loss of CHR	4	0		
Loss of MCR	2	1		
increasing WBC count	0	0		
Intolerance	69	120		
Failure to achieve CHR after 6 mths of treatment	1	0		
Failure to achieve MCR after 12 months of treatment	16	7		
Failure to achieve CCR after 24 mths of treatment	10	1		
Failure to achieve adequate PCR	54	6		
Loss of adequate PCR response	12	1		
No treatment failure	217	250		

Attachments (see zip file)	TIME TO TREATMENT FAILURE KAPLAN-MEIER
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Statistical analyses

Statistical analysis title	Time to Treatment Failure Kaplan-Meier Analysis
Statistical analysis description: Time to treatment failure is calculated as (Date of failure - Date of first dose of study medication)/30.4. Patients who have not experienced treatment failure at 5 years are censored at the earliest of (date of last visit, or the date of first dose of study medication + 1826.25 days).	
Comparison groups	Arm B v Arm A
Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Logrank

Secondary: Rate of complete haematological response

End point title	Rate of complete haematological response
End point description: To compare the dates of complete haematological response (CHR) in patients on each arm after 6 months of treatment. Patients were not evaluable if the data was missing at the timepoint required. Data were analysed as observed data and worst cases data where worst case presumes patients with a missing response are non-responders.	
End point type	Secondary
End point timeframe: 6 months	

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	406	406		
Units: number of patients				
yes	371	378		
no	22	5		
not evaluable	13	23		

Attachments (see zip file)	Complete haematological response (worst case data).pdf
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Statistical analyses

Statistical analysis title	Complete Haematologic Response(CHR)(Observed Data)
Statistical analysis description: Duration of CHR calculated as (earliest of (Date of loss of CHR, or date of treatment failure) - Date of first documentation of CHR)/30.4.	
Comparison groups	Arm B v Arm A

Number of subjects included in analysis	812
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Chi-squared

Secondary: Level of molecular responses by PCR on first line therapy

End point title	Level of molecular responses by PCR on first line therapy
End point description: The level of molecular responses (BCR-ABL/ABL ratio by real time polymerase chain reaction (international scale) (PCR) in each of the treatment arms.	
End point type	Secondary
End point timeframe: MR1 (<10%)at 3 months, MR2 (<1%) at 6 months, MR3 (<0.1%) at 12 months, MR4.5 (<0.032) at any time	

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	406	406		
Units: number of patients				
MR1 yes	264	305		
MR1 no	115	84		
not evaluable for MR1	27	17		
MR2 yes	202	277		
MR2 no	113	90		
not evaluable for MR2	91	39		
MR3 yes	181	252		
MR3 no	92	100		
not evaluable for MR3	133	54		
MR4.5 yes	231	313		
MR4.5 no	31	27		
not evaluable for MR4	144	66		

Statistical analyses

No statistical analyses for this end point

Secondary: Quality of Life

End point title	Quality of Life
End point description: Quality of life was assessed between the 2 arms. EQ-5D, FACT-G and FACT-BRM questionnaires were completed by patients during clinic visits. Data is presented graphically in attachment.	
End point type	Secondary

End point timeframe:

baseline, 3 months, 6, months, 9 months, 12 months, 18 months, 24 months, 30 months, 36 months, 42 months, 48 months, 54 months, 60 months

End point values	FAS			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: percentage	812			

Attachments (see zip file)	Quality of Life data in figures.pdf
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Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival

End point title	Overall survival
End point description: Death from any cause was considered. Overall survival censored at 2 years (24 months) and 5 years (60 months) will be compared across treatments. Data is presented for 5 years and 2 years in attachment.	
End point type	Secondary
End point timeframe: 2 years and 5 years	

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	406	406		
Units: number of events (deaths)				
0-12 months	5	5		
12-24 months	11	9		
24-36 months	19	14		
36-48 months	27	25		
48 to 60 months	34	31		

Attachments (see zip file)	Overall survival at 2 years.pdf
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Statistical analyses

No statistical analyses for this end point

Secondary: Tolerability between the regimens

End point title	Tolerability between the regimens
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End point description:

The assessment of tolerability will consist of evaluating adverse events, laboratory parameters including haematology (haemoglobin, % blasts, WBC count, platelet count) and biochemistry (total bilirubin, LDH, AST, ALT, alkaline phosphatase, creatinine and urea), physical examinations and documentation of all concomitant medications and/or therapies including blood products. Cardiovascular AEs include AEs with a preferred term of 'myocardial infarction', 'acute myocardial infarction', 'angina pectoris', 'coronary artery disease', 'acute coronary syndrome. Cytopenia AEs include AEs with a preferred term of 'anaemia', 'neutropenia' or 'thrombocytopenia'.

End point type	Secondary
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End point timeframe:

From start of study medication to 30 days after study medication stopped for each patient

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	406	406		
Units: number of patients				
Number of AEs	3801	4882		
Number of patients with AEs	398	402		
Number of SAEs	275	536		
Number of patients with SAEs	140	233		
Number of ADRs	1554	1861		
Number of patients with ADRs	360	364		
Number of serious ADRs	40	151		
Number of patients with serious ADRs	33	105		
Number of pleural effusion events	6	260		
No. of patients with pleural effusion events	6	146		
Number of pulmonary arterial hypertension events	0	1		
No. of pts with PAH events	0	1		
Number of dyspnoea events	41	141		
Number of patients with dyspnoea events	38	100		
Number of cardiovascular AEs	4	14		
Number of patients with cardiovascular AEs	4	12		
Number of cytopenia AEs	127	272		
Number of patients with cytopenia AEs	76	129		
Number of severe AEs	166	289		
Number of patients with severe AEs	109	156		
Number of AEs with tox grade 3 or 4	325	587		
No. of patients with AEs of tox grade 3 or 4	185	253		
Number of AEs leading to discontinuation	126	175		
No. of pts with AEs leading to discontinuation	89	149		
Number of AEs leading to death	22	18		
Number of patients with AEs leading to death	20	18		

Attachments (see zip file)	Uncoded AEs/S2 - AEs not able to be coded in MEDDRA Feb
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Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Occurring after starting study drug and up to 30 days after last dose

Adverse event reporting additional description:

Adverse events (AEs) collected by physician, reported by patient or from laboratory tests. AEs were defined as any undesirable sign, symptom or medical condition whether considered study drug-related or not. If present before starting study drug, they are only considered AEs if they worsen after starting study drug.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20
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Reporting groups

Reporting group title	Imatinib 400mg daily
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Reporting group description:

Imatinib 400mg daily

Reporting group title	Dasatinib 100mg daily
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Reporting group description:

Dasatinib 100mg daily

Serious adverse events	Imatinib 400mg daily	Dasatinib 100mg daily	
Total subjects affected by serious adverse events			
subjects affected / exposed	141 / 406 (34.73%)	234 / 406 (57.64%)	
number of deaths (all causes)	34	31	
number of deaths resulting from adverse events	20	18	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ACUTE LYMPHOCYTIC LEUKAEMIA			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
ACUTE MYELOID LEUKAEMIA			
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
ADENOCARCINOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

B PRECURSOR TYPE ACUTE LEUKAEMIA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-CELL LYMPHOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BASAL CELL CARCINOMA			
subjects affected / exposed	3 / 406 (0.74%)	5 / 406 (1.23%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLAST CELL CRISIS			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
BLAST CRISIS IN MYELOGENOUS LEUKAEMIA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
BREAST CANCER			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
CHOLANGIOCARCINOMA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

CHRONIC MYELOID LEUKAEMIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLON CANCER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIFFUSE LARGE B-CELL LYMPHOMA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOMETRIAL CANCER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOMETRIAL CANCER METASTATIC			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
FOCAL NODULAR HYPERPLASIA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC CANCER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
INTRADUCTAL PROLIFERATIVE BREAST LESION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
KERATOACANTHOMA			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
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	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
LYMPHOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
MENINGIOMA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENINGIOMA MALIGNANT			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTASES TO RECTUM			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
METASTASIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYELODYSPLASTIC SYNDROME			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARATHYROID TUMOUR BENIGN			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLASMA CELL MYELOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
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	4 / 406 (0.99%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTAL ADENOMA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CANCER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL ONCOCYTOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA OF LUNG			

subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
TERATOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UTERINE LEIOMYOMA			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
AORTIC ANEURYSM			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
AORTIC STENOSIS			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIAL STENOSIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEEP VEIN THROMBOSIS			
subjects affected / exposed	4 / 406 (0.99%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATOMA			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGE			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTENSION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTENSION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
INTERMITTENT CLAUDICATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERNAL HAEMORRHAGE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHOEDEMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ARTERY OCCLUSION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ISCHAEMIA			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOSIS			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASODILATATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
BREAST OPERATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLECYSTECTOMY			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERNIA REPAIR			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIP ARTHROPLASTY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
JOINT DEBRIDEMENT			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
ADVERSE DRUG REACTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

CATHETER SITE EXTRAVASATION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CATHETER SITE HAEMORRHAGE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHEST PAIN			
subjects affected / exposed	2 / 406 (0.49%)	10 / 406 (2.46%)	
occurrences causally related to treatment / all	0 / 2	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
DISEASE PROGRESSION			
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	1 / 3	1 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERALISED OEDEMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUCOSAL ULCERATION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-CARDIAC CHEST PAIN			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OEDEMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OEDEMA PERIPHERAL			
subjects affected / exposed	3 / 406 (0.74%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYREXIA			
subjects affected / exposed	3 / 406 (0.74%)	12 / 406 (2.96%)	
occurrences causally related to treatment / all	1 / 3	6 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRUG HYPERSENSITIVITY			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERSENSITIVITY			

subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
DYSMENORRHOEA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENORRHAGIA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OEDEMA GENITAL			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PRIAPISM			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TESTICULAR SWELLING			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			

subjects affected / exposed	2 / 406 (0.49%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
COUGH			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPHONIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA			
subjects affected / exposed	3 / 406 (0.74%)	7 / 406 (1.72%)	
occurrences causally related to treatment / all	0 / 3	3 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
EMPHYSEMA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPISTAXIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOPTYSIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOTHORAX			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOXIA			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
subjects affected / exposed	1 / 406 (0.25%)	56 / 406 (13.79%)	
occurrences causally related to treatment / all	0 / 1	61 / 65	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURITIC PAIN			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY ARTERIAL HYPERTENSION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
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 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY HYPERTENSION			

subjects affected / exposed	0 / 406 (0.00%)	4 / 406 (0.99%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY OEDEMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
DEPRESSION			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MAJOR DEPRESSION			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENTAL DISORDER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSYCHOTIC DISORDER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			

ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD UREA INCREASED			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ELECTROCARDIOGRAM ST-T SEGMENT ABNORMAL			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Injury, poisoning and procedural complications			
ACCIDENTAL OVERDOSE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANKLE FRACTURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CATARACT OPERATION COMPLICATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FACIAL BONES FRACTURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
FALL			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
HUMERUS FRACTURE			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INJURY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTENTIONAL OVERDOSE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
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	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
JOINT INJURY			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LACERATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUMBAR VERTEBRAL FRACTURE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OPEN FRACTURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RIB FRACTURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SOFT TISSUE INJURY			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STERNAL FRACTURE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNOVIAL RUPTURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSFUSION REACTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER LIMB FRACTURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
ATRIAL SEPTAL DEFECT			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ICHTHYOSIS			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
AGONAL RHYTHM			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
ANGINA PECTORIS			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARRHYTHMIA			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FIBRILLATION			
subjects affected / exposed	7 / 406 (1.72%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	0 / 9	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FLUTTER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIOVENTRICULAR BLOCK			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRADYCARDIA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ARREST			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
CARDIAC FAILURE			
subjects affected / exposed	4 / 406 (0.99%)	4 / 406 (0.99%)	
occurrences causally related to treatment / all	0 / 4	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC TAMPONADE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIOMEGALY			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
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 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYANOSIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL INFARCTION			
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
PALPITATIONS			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 406 (0.00%)	5 / 406 (1.23%)	
occurrences causally related to treatment / all	0 / 0	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERICARDITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUPRAVENTRICULAR TACHYCARDIA			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (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			
AMNESIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BALANCE DISORDER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CENTRAL NERVOUS SYSTEM HAEMORRHAGE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
CEREBELLAR HAEMORRHAGE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	2 / 406 (0.49%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
DIZZINESS			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEADACHE			

subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ISCHAEMIC STROKE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LACUNAR INFARCTION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOSS OF CONSCIOUSNESS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MIGRAINE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OPTIC NEURITIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PRESYNCOPE			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEIZURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SOMNOLENCE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPEECH DISORDER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNCOPE			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	2 / 406 (0.49%)	4 / 406 (0.99%)	
occurrences causally related to treatment / all	2 / 2	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYTOPENIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHADENOPATHY			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIA			
subjects affected / exposed	3 / 406 (0.74%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOSIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
MENIERE'S DISEASE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MIDDLE EAR EFFUSION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VERTIGO POSITIONAL			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
CORNEAL PERFORATION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EYE OEDEMA			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EYE SWELLING			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MACULAR DEGENERATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RETINAL DETACHMENT			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VITREOUS HAEMORRHAGE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ABDOMINAL HERNIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL HERNIA OBSTRUCTIVE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
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 / 406 (0.49%)	6 / 406 (1.48%)	
occurrences causally related to treatment / all	0 / 2	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL PAIN LOWER			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANAL FISSURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASCITES			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
BARRETT'S OESOPHAGUS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLITIS			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONSTIPATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CROHN'S DISEASE			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIARRHOEA			
subjects affected / exposed	1 / 406 (0.25%)	9 / 406 (2.22%)	
occurrences causally related to treatment / all	0 / 1	4 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULUM			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DUODENAL STENOSIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPHAGIA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCUTANEOUS FISTULA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EROSIVE DUODENITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC MUCOSAL LESION			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC ULCER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
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 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
HAEMATEMESIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL PERFORATION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINAL STENOSIS			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINE PERFORATION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATITIS ACUTE			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTAL HAEMORRHAGE			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			
subjects affected / exposed	2 / 406 (0.49%)	5 / 406 (1.23%)	
occurrences causally related to treatment / all	1 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
BILIARY COLIC			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLECYSTITIS			

subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
GALLBLADDER PAIN			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC CIRRHOSIS			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Skin and subcutaneous tissue disorders			
ANGIOEDEMA			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ERYTHEMA MULTIFORME			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERSENSITIVITY VASCULITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIVASCULAR DERMATITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH MACULAR			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN REACTION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SWELLING FACE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULITIC RASH			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	2 / 406 (0.49%)	4 / 406 (0.99%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATURIA			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEPHROLITHIASIS			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEPHROTIC SYNDROME			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POLLAKIURIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETHRAL DISORDER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETHRAL STENOSIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY RETENTION			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THYROID MASS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
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			
ARTHRALGIA			
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

ARTHRITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACK PAIN			
subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
BONE EROSION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BONE INFARCTION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COSTOCHONDRITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLANK PAIN			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FRACTURE NONUNION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GROIN PAIN			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMARTHROSIS			

subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MOBILITY DECREASED			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYALGIA			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
NECK PAIN			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEITIS DEFORMANS			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEOARTHRITIS			

subjects affected / exposed	4 / 406 (0.99%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEONECROSIS			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIARTHRTIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ROTATOR CUFF SYNDROME			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL OSTEOARTHRITIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL PAIN			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNOVITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
ABSCCESS LIMB			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANAL ABSCESS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
APPENDICITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERIAL DISEASE CARRIER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERIAL INFECTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BILIARY SEPSIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHITIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAMPYLOBACTER GASTROENTERITIS			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS			
subjects affected / exposed	4 / 406 (0.99%)	16 / 406 (3.94%)	
occurrences causally related to treatment / all	1 / 4	3 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLONIC ABSCESS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYSTITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DERMATITIS INFECTED			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED INFECTION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED SEPSIS			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULITIS			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOCARDITIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ERYSIPELAS			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOLLICULITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FUNGAL INFECTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS			
subjects affected / exposed	2 / 406 (0.49%)	8 / 406 (1.97%)	
occurrences causally related to treatment / all	0 / 2	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS ASTROVIRAL			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS NOROVIRUS			

subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 406 (0.00%)	4 / 406 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL INFECTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
H1N1 INFLUENZA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERPES ZOSTER			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTION			
subjects affected / exposed	2 / 406 (0.49%)	4 / 406 (0.99%)	
occurrences causally related to treatment / all	0 / 2	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFLUENZA			
subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
KIDNEY INFECTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOCALISED INFECTION			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	8 / 406 (1.97%)	14 / 406 (3.45%)	
occurrences causally related to treatment / all	0 / 8	2 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFECTION			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIC SEPSIS			
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	3 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORCHITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OTITIS EXTERNA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAROTITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERINEAL INFECTION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIORBITAL CELLULITIS			

subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOCYSTIS JIROVECI PNEUMONIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
subjects affected / exposed	8 / 406 (1.97%)	15 / 406 (3.69%)	
occurrences causally related to treatment / all	0 / 8	1 / 15	
deaths causally related to treatment / all	0 / 3	0 / 1	
PNEUMONIA PNEUMOCOCCAL			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL CELLULITIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYELONEPHRITIS ACUTE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY TRACT INFECTION VIRAL			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SCARLET FEVER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			
subjects affected / exposed	5 / 406 (1.23%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	1 / 5	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
STITCH ABSCESS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STREPTOCOCCAL INFECTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUBERCULOSIS			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 406 (0.49%)	5 / 406 (1.23%)	
occurrences causally related to treatment / all	0 / 2	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
UROSEPSIS			

subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL INFECTION			
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL SEPSIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL TONSILLITIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND INFECTION			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLUID RETENTION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GOUT			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERGLYCAEMIA			

subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERKALAEMIA			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERNATRAEMIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOGLYCAEMIA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOKALAEMIA			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPONATRAEMIA			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Imatinib 400mg daily	Dasatinib 100mg daily	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	394 / 406 (97.04%)	392 / 406 (96.55%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADRENAL ADENOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
B-CELL LYMPHOMA			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
BASAL CELL CARCINOMA			
subjects affected / exposed	4 / 406 (0.99%)	1 / 406 (0.25%)	
occurrences (all)	8	1	
BENIGN BREAST NEOPLASM			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
BENIGN NEOPLASM			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
FIBROADENOMA OF BREAST			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
LIPOMA			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	2	2	
MELANOCYTIC NAEVUS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
PROSTATE CANCER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
SARCOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
SCHWANNOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
SKIN PAPILLOMA			
subjects affected / exposed	3 / 406 (0.74%)	1 / 406 (0.25%)	
occurrences (all)	4	1	
UTERINE LEIOMYOMA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			

ANGIODYSPLASIA		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
FLUSHING		
subjects affected / exposed	3 / 406 (0.74%)	9 / 406 (2.22%)
occurrences (all)	3	9
HAEMATOMA		
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	2	3
HOT FLUSH		
subjects affected / exposed	7 / 406 (1.72%)	14 / 406 (3.45%)
occurrences (all)	7	14
HYPERTENSION		
subjects affected / exposed	5 / 406 (1.23%)	12 / 406 (2.96%)
occurrences (all)	5	13
HYPOTENSION		
subjects affected / exposed	4 / 406 (0.99%)	1 / 406 (0.25%)
occurrences (all)	4	1
LYMPHOEDEMA		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
ORTHOSTATIC HYPOTENSION		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
PERIPHERAL COLDNESS		
subjects affected / exposed	3 / 406 (0.74%)	6 / 406 (1.48%)
occurrences (all)	3	6
PERIPHERAL ISCHAEMIA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PHLEBITIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
RAYNAUD'S PHENOMENON		
subjects affected / exposed	2 / 406 (0.49%)	3 / 406 (0.74%)
occurrences (all)	2	3

THROMBOPHLEBITIS			
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)	
occurrences (all)	1	3	
THROMBOSIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	2	
VARICOSE VEIN			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	1	1	
Surgical and medical procedures			
ABSCESS DRAINAGE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
ANOPLASTY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
CANCER SURGERY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
CATARACT OPERATION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
CIRCUMCISION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
FINGER REPAIR OPERATION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
INGUINAL HERNIA REPAIR			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
KNEE ARTHROPLASTY			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
LIPOMA EXCISION			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
MANIPULATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
MOLE EXCISION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
NASAL SEPTAL OPERATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
SALPINGO-OOPHORECTOMY BILATERAL			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
SKIN NEOPLASM EXCISION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
TONSILLECTOMY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
TOOTH EXTRACTION			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
UMBILICAL HERNIA REPAIR			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
UVULECTOMY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
ADVERSE DRUG REACTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
ASTHENIA			

subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	2	2
AXILLARY PAIN		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
CHEST DISCOMFORT		
subjects affected / exposed	5 / 406 (1.23%)	7 / 406 (1.72%)
occurrences (all)	5	7
CHEST PAIN		
subjects affected / exposed	12 / 406 (2.96%)	24 / 406 (5.91%)
occurrences (all)	13	27
CHILLS		
subjects affected / exposed	5 / 406 (1.23%)	8 / 406 (1.97%)
occurrences (all)	5	8
CYST		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
DISCOMFORT		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
FACE OEDEMA		
subjects affected / exposed	7 / 406 (1.72%)	5 / 406 (1.23%)
occurrences (all)	7	5
FATIGUE		
subjects affected / exposed	123 / 406 (30.30%)	147 / 406 (36.21%)
occurrences (all)	146	196
FEELING ABNORMAL		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
FEELING COLD		
subjects affected / exposed	4 / 406 (0.99%)	8 / 406 (1.97%)
occurrences (all)	4	8
FEELING HOT		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
GENERALISED OEDEMA		

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
GRANULOMA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
HERNIA		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
HERNIA PAIN		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HUNGER		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
INFLUENZA LIKE ILLNESS		
subjects affected / exposed	14 / 406 (3.45%)	17 / 406 (4.19%)
occurrences (all)	20	18
LOCAL SWELLING		
subjects affected / exposed	1 / 406 (0.25%)	6 / 406 (1.48%)
occurrences (all)	1	8
LOCALISED OEDEMA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
MALAISE		
subjects affected / exposed	6 / 406 (1.48%)	10 / 406 (2.46%)
occurrences (all)	6	11
MASS		
subjects affected / exposed	1 / 406 (0.25%)	6 / 406 (1.48%)
occurrences (all)	1	7
MUCOSAL INFLAMMATION		
subjects affected / exposed	3 / 406 (0.74%)	3 / 406 (0.74%)
occurrences (all)	3	3
NODULE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
NON-CARDIAC CHEST PAIN		

subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
OEDEMA		
subjects affected / exposed	8 / 406 (1.97%)	5 / 406 (1.23%)
occurrences (all)	8	5
OEDEMA PERIPHERAL		
subjects affected / exposed	31 / 406 (7.64%)	17 / 406 (4.19%)
occurrences (all)	40	22
PAIN		
subjects affected / exposed	18 / 406 (4.43%)	16 / 406 (3.94%)
occurrences (all)	20	16
PERIPHERAL SWELLING		
subjects affected / exposed	14 / 406 (3.45%)	6 / 406 (1.48%)
occurrences (all)	16	7
POLYP		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PYREXIA		
subjects affected / exposed	9 / 406 (2.22%)	18 / 406 (4.43%)
occurrences (all)	10	22
SENSATION OF BLOOD FLOW		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
SUPRAPUBIC PAIN		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
SWELLING		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
TEMPERATURE INTOLERANCE		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	2
TENDERNESS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
THIRST		

subjects affected / exposed occurrences (all)	3 / 406 (0.74%) 3	1 / 406 (0.25%) 1	
ULCER subjects affected / exposed occurrences (all)	0 / 406 (0.00%) 0	1 / 406 (0.25%) 1	
Immune system disorders DRUG HYPERSENSITIVITY subjects affected / exposed occurrences (all)	2 / 406 (0.49%) 2	6 / 406 (1.48%) 6	
HYPERSENSITIVITY subjects affected / exposed occurrences (all)	1 / 406 (0.25%) 1	2 / 406 (0.49%) 2	
HYPOGAMMAGLOBULINAEMIA subjects affected / exposed occurrences (all)	1 / 406 (0.25%) 1	0 / 406 (0.00%) 0	
SEASONAL ALLERGY subjects affected / exposed occurrences (all)	2 / 406 (0.49%) 2	10 / 406 (2.46%) 10	
Social circumstances MENOPAUSE subjects affected / exposed occurrences (all)	0 / 406 (0.00%) 0	1 / 406 (0.25%) 1	
Reproductive system and breast disorders BENIGN PROSTATIC HYPERPLASIA subjects affected / exposed occurrences (all)	0 / 406 (0.00%) 0	1 / 406 (0.25%) 1	
BREAST DISCHARGE subjects affected / exposed occurrences (all)	0 / 406 (0.00%) 0	1 / 406 (0.25%) 1	
BREAST MASS subjects affected / exposed occurrences (all)	1 / 406 (0.25%) 1	1 / 406 (0.25%) 2	
BREAST OEDEMA subjects affected / exposed occurrences (all)	0 / 406 (0.00%) 0	1 / 406 (0.25%) 1	
BREAST PAIN			

subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
BREAST SWELLING		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
BREAST TENDERNESS		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
CERVICAL DYSPLASIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
DYSMENORRHOEA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	2	0
ENDOMETRIOSIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
ERECTILE DYSFUNCTION		
subjects affected / exposed	5 / 406 (1.23%)	2 / 406 (0.49%)
occurrences (all)	6	2
GENITAL PAIN		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
GYNAECOMASTIA		
subjects affected / exposed	2 / 406 (0.49%)	5 / 406 (1.23%)
occurrences (all)	2	6
MENORRHAGIA		
subjects affected / exposed	5 / 406 (1.23%)	7 / 406 (1.72%)
occurrences (all)	6	8
MENSTRUATION IRREGULAR		
subjects affected / exposed	4 / 406 (0.99%)	3 / 406 (0.74%)
occurrences (all)	4	3
METRORRHAGIA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
NIPPLE PAIN		

subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
OEDEMA GENITAL		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
OVARIAN CYST		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PELVIC PAIN		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
PENILE PAIN		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
PENILE SWELLING		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PERINEAL PAIN		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
POLYMENORRHOEA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PRIAPISM		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PROSTATITIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PROSTATOMEGALY		
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	2	2
SCROTAL OEDEMA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
TESTICULAR PAIN		

subjects affected / exposed	1 / 406 (0.25%)	5 / 406 (1.23%)	
occurrences (all)	1	5	
TESTICULAR SWELLING			
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)	
occurrences (all)	2	2	
VAGINAL CYST			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 406 (0.00%)	7 / 406 (1.72%)	
occurrences (all)	0	8	
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	2 / 406 (0.49%)	3 / 406 (0.74%)	
occurrences (all)	2	4	
ATELECTASIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
BRONCHOSPASM			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
CATARRH			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	2 / 406 (0.49%)	3 / 406 (0.74%)	
occurrences (all)	2	3	
COUGH			
subjects affected / exposed	30 / 406 (7.39%)	60 / 406 (14.78%)	
occurrences (all)	32	70	
DIAPHRAGMALGIA			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
DRY THROAT		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
DYSPHONIA		
subjects affected / exposed	3 / 406 (0.74%)	4 / 406 (0.99%)
occurrences (all)	3	4
DYSPNOEA		
subjects affected / exposed	35 / 406 (8.62%)	99 / 406 (24.38%)
occurrences (all)	38	134
DYSPNOEA AT REST		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
DYSPNOEA EXERTIONAL		
subjects affected / exposed	12 / 406 (2.96%)	22 / 406 (5.42%)
occurrences (all)	12	25
DYSPNOEA PAROXYSMAL NOCTURNAL		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
EPISTAXIS		
subjects affected / exposed	10 / 406 (2.46%)	8 / 406 (1.97%)
occurrences (all)	13	8
HAEMOPTYSIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
HICCUPS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
HYPOXIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
INTERSTITIAL LUNG DISEASE		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0

LARYNGEAL INFLAMMATION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
LARYNGEAL POLYP		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
LUNG CONSOLIDATION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
NASAL CONGESTION		
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)
occurrences (all)	5	2
OROPHARYNGEAL PAIN		
subjects affected / exposed	18 / 406 (4.43%)	28 / 406 (6.90%)
occurrences (all)	20	30
ORTHOPNOEA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PHARYNGEAL LEUKOPLAKIA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PHARYNGEAL OEDEMA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PLEURAL EFFUSION		
subjects affected / exposed	4 / 406 (0.99%)	108 / 406 (26.60%)
occurrences (all)	4	193
PLEURISY		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PLEURITIC PAIN		
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)
occurrences (all)	3	2
PNEUMONITIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1

PRODUCTIVE COUGH		
subjects affected / exposed	4 / 406 (0.99%)	13 / 406 (3.20%)
occurrences (all)	5	13
PULMONARY CONGESTION		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
PULMONARY EMBOLISM		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PULMONARY FIBROSIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PULMONARY HAEMORRHAGE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PULMONARY HYPERTENSION		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
PULMONARY OEDEMA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PULMONARY SARCOIDOSIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
RHINITIS ALLERGIC		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
RHINORRHOEA		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
SINUS CONGESTION		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
SINUS PAIN		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1

SLEEP APNOEA SYNDROME			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	2	1	
THROAT IRRITATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
VOCAL CORD CYST			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
WHEEZING			
subjects affected / exposed	1 / 406 (0.25%)	7 / 406 (1.72%)	
occurrences (all)	1	7	
Psychiatric disorders			
ABNORMAL DREAMS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
AFFECT LABILITY			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences (all)	2	0	
AFFECTIVE DISORDER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
AGGRESSION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
AGITATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
ANXIETY			
subjects affected / exposed	7 / 406 (1.72%)	13 / 406 (3.20%)	
occurrences (all)	7	17	
CONFUSIONAL STATE			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences (all)	1	2	
DEPRESSED MOOD			

subjects affected / exposed	7 / 406 (1.72%)	18 / 406 (4.43%)
occurrences (all)	7	19
DEPRESSION		
subjects affected / exposed	16 / 406 (3.94%)	30 / 406 (7.39%)
occurrences (all)	16	30
DEPRESSIVE SYMPTOM		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
EATING DISORDER		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
HALLUCINATION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	2	0
INSOMNIA		
subjects affected / exposed	25 / 406 (6.16%)	23 / 406 (5.67%)
occurrences (all)	26	25
IRRITABILITY		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
LIBIDO DECREASED		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
LOSS OF LIBIDO		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
MENTAL DISORDER		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
MOOD ALTERED		
subjects affected / exposed	4 / 406 (0.99%)	7 / 406 (1.72%)
occurrences (all)	4	7
MOOD SWINGS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PANIC ATTACK		

subjects affected / exposed	0 / 406 (0.00%)	4 / 406 (0.99%)	
occurrences (all)	0	4	
PERSONALITY DISORDER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
PSYCHIATRIC SYMPTOM			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	1	1	
SCHIZOPHRENIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
SLEEP DISORDER			
subjects affected / exposed	6 / 406 (1.48%)	3 / 406 (0.74%)	
occurrences (all)	6	3	
STRESS			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences (all)	1	2	
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
Product issues			
DEVICE DAMAGE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	2	1	
GALLBLADDER PAIN			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
HEPATIC CIRRHOSIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
HEPATIC FUNCTION ABNORMAL			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
HEPATIC STEATOSIS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	7 / 406 (1.72%)	5 / 406 (1.23%)	
occurrences (all)	8	10	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	1	5	
BIOPSY PROSTATE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	5 / 406 (1.23%)	0 / 406 (0.00%)	
occurrences (all)	5	0	
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	2	2	
BLOOD CALCIUM DECREASED			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)	
occurrences (all)	1	4	
BLOOD COUNT ABNORMAL			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	2	1	
BLOOD CREATININE INCREASED			

subjects affected / exposed	3 / 406 (0.74%)	3 / 406 (0.74%)
occurrences (all)	3	3
BLOOD FOLATE DECREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
BLOOD GLUCOSE INCREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
BLOOD IRON DECREASED		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
BLOOD LACTATE DEHYDROGENASE INCREASED		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
BLOOD PHOSPHORUS DECREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
BLOOD POTASSIUM DECREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
BLOOD PRESSURE INCREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
BLOOD THYROID STIMULATING HORMONE INCREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
BORRELIA TEST		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
CARDIAC MURMUR		
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)
occurrences (all)	0	3
CLOSTRIDIUM TEST POSITIVE		

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
COLONOSCOPY		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
ECHOCARDIOGRAM ABNORMAL		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
ELECTROCARDIOGRAM PR SHORTENED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
ENDOSCOPY UPPER GASTROINTESTINAL TRACT		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
GAMMA-GLUTAMYLTRANSFERASE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
GAMMA-GLUTAMYLTRANSFERASE INCREASED		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
HAEMOGLOBIN DECREASED		
subjects affected / exposed	3 / 406 (0.74%)	8 / 406 (1.97%)
occurrences (all)	3	9
INTRAOCULAR PRESSURE INCREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
LIVER FUNCTION TEST ABNORMAL		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
MENSTRUATION NORMAL		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
NEUTROPHIL COUNT		

subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	2	2
NEUTROPHIL COUNT DECREASED		
subjects affected / exposed	4 / 406 (0.99%)	7 / 406 (1.72%)
occurrences (all)	5	10
PLATELET COUNT DECREASED		
subjects affected / exposed	7 / 406 (1.72%)	11 / 406 (2.71%)
occurrences (all)	9	20
PROSTATIC SPECIFIC ANTIGEN INCREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PROTEIN URINE PRESENT		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
SERUM FERRITIN DECREASED		
subjects affected / exposed	0 / 406 (0.00%)	7 / 406 (1.72%)
occurrences (all)	0	8
STREPTOCOCCUS TEST POSITIVE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
THYROID FUNCTION TEST ABNORMAL		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
VITAMIN B12 DECREASED		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
VITAMIN D DECREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
WEIGHT DECREASED		
subjects affected / exposed	7 / 406 (1.72%)	15 / 406 (3.69%)
occurrences (all)	8	15
WEIGHT INCREASED		

subjects affected / exposed	15 / 406 (3.69%)	7 / 406 (1.72%)	
occurrences (all)	15	12	
WHITE BLOOD CELL COUNT			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	2	
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	2 / 406 (0.49%)	4 / 406 (0.99%)	
occurrences (all)	2	4	
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
ACCIDENTAL OVERDOSE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
ANKLE FRACTURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
ARTHROPOD BITE			
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)	
occurrences (all)	0	3	
AVULSION FRACTURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
CHEST INJURY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
CLAVICLE FRACTURE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
CONTUSION			
subjects affected / exposed	8 / 406 (1.97%)	9 / 406 (2.22%)	
occurrences (all)	8	9	
DENTAL RESTORATION FAILURE			

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
EPICONDYLITIS		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
EYE CONTUSION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
FALL		
subjects affected / exposed	8 / 406 (1.97%)	11 / 406 (2.71%)
occurrences (all)	9	14
FOOT FRACTURE		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
FRACTURE		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
GASTROINTESTINAL STOMA COMPLICATION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
HEAD INJURY		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
INJURY		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
JOINT DISLOCATION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
JOINT INJURY		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
LACERATION		
subjects affected / exposed	6 / 406 (1.48%)	0 / 406 (0.00%)
occurrences (all)	6	0

LIGAMENT RUPTURE		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
LIGAMENT SPRAIN		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
LIMB INJURY		
subjects affected / exposed	2 / 406 (0.49%)	3 / 406 (0.74%)
occurrences (all)	2	3
MEDICATION ERROR		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
MENISCUS INJURY		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
MUSCLE STRAIN		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	2
NECK INJURY		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
POST PROCEDURAL DISCOMFORT		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
POST PROCEDURAL HAEMORRHAGE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
POST-TRAUMATIC NECK SYNDROME		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PROCEDURAL DIZZINESS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PROCEDURAL PAIN		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1

RIB FRACTURE			
subjects affected / exposed	3 / 406 (0.74%)	1 / 406 (0.25%)	
occurrences (all)	3	1	
SOFT TISSUE INJURY			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	2	1	
SUNBURN			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences (all)	2	0	
TENDON RUPTURE			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences (all)	1	2	
THERMAL BURN			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences (all)	3	0	
UPPER LIMB FRACTURE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	2	0	
VACCINATION COMPLICATION			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
WRIST FRACTURE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	2	0	
Congenital, familial and genetic disorders			
GILBERT'S SYNDROME			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
HYDROCELE			
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)	
occurrences (all)	3	2	
PHIMOSIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			

ANGINA PECTORIS		
subjects affected / exposed	0 / 406 (0.00%)	4 / 406 (0.99%)
occurrences (all)	0	4
ARRHYTHMIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
ATRIAL FIBRILLATION		
subjects affected / exposed	3 / 406 (0.74%)	6 / 406 (1.48%)
occurrences (all)	3	7
BRADYCARDIA		
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	2	2
BUNDLE BRANCH BLOCK RIGHT		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
CARDIAC FAILURE CHRONIC		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
CARDIAC VALVE DISEASE		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
CARDIOMEGALY		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
CARDIOMYOPATHY		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
CARDIOTOXICITY		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
CONDUCTION DISORDER		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
DIASTOLIC DYSFUNCTION		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1

LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
LEFT VENTRICULAR HYPERTROPHY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences (all)	2	0	
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
PALPITATIONS			
subjects affected / exposed	9 / 406 (2.22%)	17 / 406 (4.19%)	
occurrences (all)	11	19	
PERICARDIAL EFFUSION			
subjects affected / exposed	1 / 406 (0.25%)	7 / 406 (1.72%)	
occurrences (all)	1	7	
PERICARDITIS			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	1	2	
SUPRAVENTRICULAR EXTRASYSTOLES			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
TACHYCARDIA			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
Nervous system disorders			
AGEUSIA			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	1	1	
AMNESIA			

subjects affected / exposed	2 / 406 (0.49%)	5 / 406 (1.23%)
occurrences (all)	2	5
BALANCE DISORDER		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
BURNING SENSATION		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
CAROTID ARTERY CALCIFICATION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
CARPAL TUNNEL SYNDROME		
subjects affected / exposed	0 / 406 (0.00%)	5 / 406 (1.23%)
occurrences (all)	0	6
CEREBELLAR INFARCTION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
CLUSTER HEADACHE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
COGNITIVE DISORDER		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
DEMENTIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	2
DISTURBANCE IN ATTENTION		
subjects affected / exposed	4 / 406 (0.99%)	2 / 406 (0.49%)
occurrences (all)	4	2
DIZZINESS		
subjects affected / exposed	29 / 406 (7.14%)	36 / 406 (8.87%)
occurrences (all)	31	45
DIZZINESS POSTURAL		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
DYSGEUSIA		

subjects affected / exposed	13 / 406 (3.20%)	9 / 406 (2.22%)
occurrences (all)	13	9
DYSKINESIA		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
DYSTONIA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
EXERTIONAL HEADACHE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
FACIAL PARALYSIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HEADACHE		
subjects affected / exposed	61 / 406 (15.02%)	110 / 406 (27.09%)
occurrences (all)	75	140
HYPERAESTHESIA		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
HYPOAESTHESIA		
subjects affected / exposed	11 / 406 (2.71%)	8 / 406 (1.97%)
occurrences (all)	12	9
LETHARGY		
subjects affected / exposed	39 / 406 (9.61%)	34 / 406 (8.37%)
occurrences (all)	42	37
LOSS OF CONSCIOUSNESS		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
MEMORY IMPAIRMENT		
subjects affected / exposed	3 / 406 (0.74%)	8 / 406 (1.97%)
occurrences (all)	4	8
MENTAL IMPAIRMENT		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
MIGRAINE		

subjects affected / exposed	6 / 406 (1.48%)	3 / 406 (0.74%)
occurrences (all)	6	3
NERVE COMPRESSION		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
NEURALGIA		
subjects affected / exposed	5 / 406 (1.23%)	3 / 406 (0.74%)
occurrences (all)	5	3
NEUROLOGICAL SYMPTOM		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
NEUROPATHY PERIPHERAL		
subjects affected / exposed	8 / 406 (1.97%)	5 / 406 (1.23%)
occurrences (all)	9	5
PARAESTHESIA		
subjects affected / exposed	12 / 406 (2.96%)	15 / 406 (3.69%)
occurrences (all)	14	16
PERIPHERAL MOTOR NEUROPATHY		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
PERIPHERAL SENSORY NEUROPATHY		
subjects affected / exposed	3 / 406 (0.74%)	8 / 406 (1.97%)
occurrences (all)	3	8
POOR QUALITY SLEEP		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
POST HERPETIC NEURALGIA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PRESYNCOPE		
subjects affected / exposed	3 / 406 (0.74%)	0 / 406 (0.00%)
occurrences (all)	3	0
RESTLESS LEGS SYNDROME		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
SCIATICA		

subjects affected / exposed	4 / 406 (0.99%)	7 / 406 (1.72%)	
occurrences (all)	5	8	
SEIZURE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
SENSORY DISTURBANCE			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
SOMNOLENCE			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	3	1	
SPEECH DISORDER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
SYNCOPE			
subjects affected / exposed	5 / 406 (1.23%)	4 / 406 (0.99%)	
occurrences (all)	5	4	
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	3	1	
TREMOR			
subjects affected / exposed	1 / 406 (0.25%)	6 / 406 (1.48%)	
occurrences (all)	1	7	
VASCULAR DEMENTIA			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
VISUAL FIELD DEFECT			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	27 / 406 (6.65%)	40 / 406 (9.85%)	
occurrences (all)	34	66	
BICYTOPENIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	

BONE MARROW FAILURE		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
COAGULOPATHY		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
CYTOPENIA		
subjects affected / exposed	4 / 406 (0.99%)	4 / 406 (0.99%)
occurrences (all)	4	4
HAEMATOTOXICITY		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
INCREASED TENDENCY TO BRUISE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
IRON DEFICIENCY ANAEMIA		
subjects affected / exposed	4 / 406 (0.99%)	3 / 406 (0.74%)
occurrences (all)	4	3
LEUKOCYTOSIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
LEUKOPENIA		
subjects affected / exposed	3 / 406 (0.74%)	3 / 406 (0.74%)
occurrences (all)	3	3
LYMPHADENITIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
LYMPHADENOPATHY		
subjects affected / exposed	1 / 406 (0.25%)	9 / 406 (2.22%)
occurrences (all)	1	9
LYMPHOCYTOSIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
NEUTROPENIA		
subjects affected / exposed	37 / 406 (9.11%)	49 / 406 (12.07%)
occurrences (all)	60	94

NEUTROPHILIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
PANCYTOPENIA			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
POLYCYTHAEMIA			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
SPLENIC INFARCTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
SPLENOMEGALY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
THROMBOCYTOPENIA			
subjects affected / exposed	23 / 406 (5.67%)	65 / 406 (16.01%)	
occurrences (all)	28	106	
THROMBOCYTOPENIC PURPURA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
THROMBOCYTOSIS			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
DEAFNESS			
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)	
occurrences (all)	2	2	
DEAFNESS UNILATERAL			
subjects affected / exposed	3 / 406 (0.74%)	1 / 406 (0.25%)	
occurrences (all)	3	1	
EAR CONGESTION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
EAR DISCOMFORT			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
EAR HAEMORRHAGE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
EAR PAIN		
subjects affected / exposed	5 / 406 (1.23%)	5 / 406 (1.23%)
occurrences (all)	5	5
EXCESSIVE CERUMEN PRODUCTION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
EXTERNAL EAR PAIN		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HYPERACUSIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
HYPOACUSIS		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
MENIERE'S DISEASE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
MIDDLE EAR DISORDER		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
OTORRHOEA		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
TINNITUS		
subjects affected / exposed	4 / 406 (0.99%)	8 / 406 (1.97%)
occurrences (all)	4	8
TYMPANIC MEMBRANE PERFORATION		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0

VERTIGO			
subjects affected / exposed	3 / 406 (0.74%)	7 / 406 (1.72%)	
occurrences (all)	3	8	
VERTIGO POSITIONAL			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
ANGLE CLOSURE GLAUCOMA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
ASTHENOPIA			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	2	1	
BLEPHARAL PIGMENTATION			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
BLEPHARITIS			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	1	1	
BLEPHAROSPASM			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences (all)	1	2	
BLINDNESS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
CATARACT			
subjects affected / exposed	2 / 406 (0.49%)	4 / 406 (0.99%)	
occurrences (all)	2	4	
CATARACT NUCLEAR			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	8 / 406 (1.97%)	1 / 406 (0.25%)	
occurrences (all)	8	1	
CONJUNCTIVITIS ALLERGIC			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
DIABETIC RETINOPATHY		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
DIPLOPIA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
DRY AGE-RELATED MACULAR DEGENERATION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
DRY EYE		
subjects affected / exposed	10 / 406 (2.46%)	7 / 406 (1.72%)
occurrences (all)	11	7
ERYTHEMA OF EYELID		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
EYE ALLERGY		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
EYE DISCHARGE		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	3
EYE HAEMORRHAGE		
subjects affected / exposed	4 / 406 (0.99%)	1 / 406 (0.25%)
occurrences (all)	5	1
EYE INFLAMMATION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
EYE OEDEMA		
subjects affected / exposed	13 / 406 (3.20%)	3 / 406 (0.74%)
occurrences (all)	15	3
EYE PAIN		
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)
occurrences (all)	3	2

EYE PRURITUS		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
EYE SWELLING		
subjects affected / exposed	36 / 406 (8.87%)	8 / 406 (1.97%)
occurrences (all)	40	10
EYE ULCER		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
EYELID OEDEMA		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	3	1
GLAUCOMA		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
IRITIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
KERATOCONUS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
LACRIMATION INCREASED		
subjects affected / exposed	15 / 406 (3.69%)	4 / 406 (0.99%)
occurrences (all)	15	4
MACULAR DEGENERATION		
subjects affected / exposed	3 / 406 (0.74%)	0 / 406 (0.00%)
occurrences (all)	3	0
MACULAR FIBROSIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
MACULAR OEDEMA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
OCULAR HYPERAEMIA		
subjects affected / exposed	7 / 406 (1.72%)	7 / 406 (1.72%)
occurrences (all)	11	7

OCULAR HYPERTENSION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
ORBITAL OEDEMA		
subjects affected / exposed	5 / 406 (1.23%)	0 / 406 (0.00%)
occurrences (all)	5	0
PERIORBITAL OEDEMA		
subjects affected / exposed	50 / 406 (12.32%)	22 / 406 (5.42%)
occurrences (all)	58	28
PHOTOPHOBIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PHOTOPSIA		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
RETINAL DETACHMENT		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
RETINAL HAEMORRHAGE		
subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)
occurrences (all)	1	4
RETINOPATHY		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
RETINOPATHY HYPERTENSIVE		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
SCLERAL HAEMORRHAGE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
SWOLLEN TEAR DUCT		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
VISION BLURRED		
subjects affected / exposed	11 / 406 (2.71%)	11 / 406 (2.71%)
occurrences (all)	13	13

VISUAL IMPAIRMENT			
subjects affected / exposed	4 / 406 (0.99%)	5 / 406 (1.23%)	
occurrences (all)	4	7	
VITREOUS FLOATERS			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences (all)	1	2	
VITREOUS HAEMORRHAGE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	14 / 406 (3.45%)	13 / 406 (3.20%)	
occurrences (all)	17	13	
ABDOMINAL DISTENSION			
subjects affected / exposed	10 / 406 (2.46%)	11 / 406 (2.71%)	
occurrences (all)	11	13	
ABDOMINAL HERNIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
ABDOMINAL PAIN			
subjects affected / exposed	40 / 406 (9.85%)	39 / 406 (9.61%)	
occurrences (all)	42	45	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	15 / 406 (3.69%)	17 / 406 (4.19%)	
occurrences (all)	16	18	
ABDOMINAL PAIN LOWER			
subjects affected / exposed	4 / 406 (0.99%)	4 / 406 (0.99%)	
occurrences (all)	4	4	
ABDOMINAL TENDERNESS			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
ANAL FISSURE			
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)	
occurrences (all)	1	3	
ANAL FISTULA			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
ANAL INCONTINENCE		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
ANAL POLYP		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
ANORECTAL DISCOMFORT		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
ASCITES		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
BOWEL MOVEMENT IRREGULARITY		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
BUCCAL MUCOSAL ROUGHENING		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
CHANGE OF BOWEL HABIT		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
COLITIS		
subjects affected / exposed	0 / 406 (0.00%)	4 / 406 (0.99%)
occurrences (all)	0	4
CROHN'S DISEASE		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	2	1
CONSTIPATION		
subjects affected / exposed	22 / 406 (5.42%)	54 / 406 (13.30%)
occurrences (all)	24	64
DENTAL CARIES		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
DIARRHOEA		

subjects affected / exposed	151 / 406 (37.19%)	112 / 406 (27.59%)
occurrences (all)	204	160
DIVERTICULUM		
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	2	2
DRY MOUTH		
subjects affected / exposed	4 / 406 (0.99%)	2 / 406 (0.49%)
occurrences (all)	4	2
DUODENAL ULCER		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
DYSPEPSIA		
subjects affected / exposed	35 / 406 (8.62%)	20 / 406 (4.93%)
occurrences (all)	43	24
DYSPHAGIA		
subjects affected / exposed	2 / 406 (0.49%)	5 / 406 (1.23%)
occurrences (all)	2	5
EPIGASTRIC DISCOMFORT		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
FAECES DISCOLOURED		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
FAECES SOFT		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
FLATULENCE		
subjects affected / exposed	9 / 406 (2.22%)	9 / 406 (2.22%)
occurrences (all)	10	9
FOOD POISONING		
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)
occurrences (all)	3	2
FREQUENT BOWEL MOVEMENTS		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
GASTRIC ANTRAL VASCULAR		

ECTASIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
GASTRIC ULCER		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
GASTRITIS		
subjects affected / exposed	2 / 406 (0.49%)	5 / 406 (1.23%)
occurrences (all)	2	5
GASTRITIS EROSIVE		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
GASTRITIS HAEMORRHAGIC		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
GASTROINTESTINAL DISORDER		
subjects affected / exposed	5 / 406 (1.23%)	1 / 406 (0.25%)
occurrences (all)	5	1
GASTROINTESTINAL HAEMORRHAGE		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
GASTROINTESTINAL INFLAMMATION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
GASTROOESOPHAGEAL REFLUX DISEASE		
subjects affected / exposed	7 / 406 (1.72%)	5 / 406 (1.23%)
occurrences (all)	8	5
GINGIVAL BLEEDING		
subjects affected / exposed	4 / 406 (0.99%)	2 / 406 (0.49%)
occurrences (all)	4	2
GINGIVAL PAIN		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
GLOSSODYNIA		

subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	2	2
HAEMATEMESIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HAEMATOCHESIA		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
HAEMORRHOIDAL HAEMORRHAGE		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
HAEMORRHOIDS		
subjects affected / exposed	4 / 406 (0.99%)	7 / 406 (1.72%)
occurrences (all)	4	8
HIATUS HERNIA		
subjects affected / exposed	4 / 406 (0.99%)	2 / 406 (0.49%)
occurrences (all)	4	2
HYPERCHLORHYDRIA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
ILEUS PARALYTIC		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
IRRITABLE BOWEL SYNDROME		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
LARGE INTESTINE POLYP		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
LIP DRY		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
LIP PAIN		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
LIP SWELLING		

subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
MELAENA		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
MOUTH CYST		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
MOUTH HAEMORRHAGE		
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)
occurrences (all)	0	3
MOUTH ULCERATION		
subjects affected / exposed	17 / 406 (4.19%)	27 / 406 (6.65%)
occurrences (all)	17	40
NAUSEA		
subjects affected / exposed	146 / 406 (35.96%)	108 / 406 (26.60%)
occurrences (all)	180	125
ODYNOPHAGIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
OESOPHAGITIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
ORAL MUCOSAL BLISTERING		
subjects affected / exposed	3 / 406 (0.74%)	0 / 406 (0.00%)
occurrences (all)	3	0
ORAL PAIN		
subjects affected / exposed	0 / 406 (0.00%)	4 / 406 (0.99%)
occurrences (all)	0	4
PAROTID GLAND ENLARGEMENT		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
POUCHITIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PROCTALGIA		

subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)
occurrences (all)	1	4
RECTAL DISCHARGE		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
RECTAL HAEMORRHAGE		
subjects affected / exposed	9 / 406 (2.22%)	7 / 406 (1.72%)
occurrences (all)	9	7
RECTAL POLYP		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	5	1
REFLUX GASTRITIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
RETCHING		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
SPLENIC ARTERY ANEURYSM		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
STOMATITIS		
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)
occurrences (all)	1	3
SWOLLEN TONGUE		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
TONGUE BLISTERING		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
TONGUE COATED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
TONGUE OEDEMA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
TONGUE ULCERATION		

subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences (all)	3	0	
TOOTH DISORDER			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
TOOTH EROSION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
TOOTH IMPACTED			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences (all)	2	0	
TOOTH LOSS			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	1	1	
TOOTHACHE			
subjects affected / exposed	3 / 406 (0.74%)	7 / 406 (1.72%)	
occurrences (all)	3	8	
VOMITING			
subjects affected / exposed	67 / 406 (16.50%)	53 / 406 (13.05%)	
occurrences (all)	81	64	
UMBILICAL HERNIA			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 406 (0.00%)	12 / 406 (2.96%)	
occurrences (all)	0	13	
ACTINIC KERATOSIS			
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	2	1	
ALOPECIA			
subjects affected / exposed	22 / 406 (5.42%)	21 / 406 (5.17%)	
occurrences (all)	23	21	
BLISTER			
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)	
occurrences (all)	3	2	

BLOOD BLISTER		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
COLD SWEAT		
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)
occurrences (all)	0	3
DERMAL CYST		
subjects affected / exposed	4 / 406 (0.99%)	1 / 406 (0.25%)
occurrences (all)	4	1
DERMATITIS		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
DERMATITIS ACNEIFORM		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	3
DERMATITIS ALLERGIC		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
DERMATITIS CONTACT		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
DERMATOSIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
DIABETIC FOOT		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
DRY SKIN		
subjects affected / exposed	21 / 406 (5.17%)	21 / 406 (5.17%)
occurrences (all)	22	24
ECZEMA		
subjects affected / exposed	7 / 406 (1.72%)	8 / 406 (1.97%)
occurrences (all)	8	8
ERYTHEMA		
subjects affected / exposed	5 / 406 (1.23%)	7 / 406 (1.72%)
occurrences (all)	6	7

ERYTHEMA NODOSUM		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
EXCESSIVE SKIN		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
EXFOLIATIVE RASH		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
FORDYCE SPOTS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HAIR COLOUR CHANGES		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HAIR GROWTH ABNORMAL		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
HAND DERMATITIS		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
HYPERHIDROSIS		
subjects affected / exposed	6 / 406 (1.48%)	13 / 406 (3.20%)
occurrences (all)	6	13
HYPERKERATOSIS		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
INGROWING NAIL		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
INTERTRIGO		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
LICHEN PLANUS		
subjects affected / exposed	3 / 406 (0.74%)	0 / 406 (0.00%)
occurrences (all)	3	0

LICHEN SCLEROSUS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
MILIARIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
NAIL DISCOLOURATION		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
NAIL RIDGING		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
NIGHT SWEATS		
subjects affected / exposed	13 / 406 (3.20%)	16 / 406 (3.94%)
occurrences (all)	13	16
ONYCHOCCLASIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
ONYCHOMADESIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PAIN OF SKIN		
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)
occurrences (all)	1	3
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
PETECHIAE		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	2
PHOTOSENSITIVITY REACTION		
subjects affected / exposed	2 / 406 (0.49%)	5 / 406 (1.23%)
occurrences (all)	2	6
PIGMENTATION DISORDER		

subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PRURITUS		
subjects affected / exposed	20 / 406 (4.93%)	27 / 406 (6.65%)
occurrences (all)	23	30
PRURITUS GENERALISED		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PSORIASIS		
subjects affected / exposed	2 / 406 (0.49%)	5 / 406 (1.23%)
occurrences (all)	2	6
PURPURA		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
RASH		
subjects affected / exposed	77 / 406 (18.97%)	119 / 406 (29.31%)
occurrences (all)	92	160
RASH ERYTHEMATOUS		
subjects affected / exposed	6 / 406 (1.48%)	4 / 406 (0.99%)
occurrences (all)	6	4
RASH FOLLICULAR		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
RASH GENERALISED		
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)
occurrences (all)	0	3
RASH MACULAR		
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	2	2
RASH MACULO-PAPULAR		
subjects affected / exposed	4 / 406 (0.99%)	11 / 406 (2.71%)
occurrences (all)	4	14
RASH PAPULAR		
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)
occurrences (all)	1	3
RASH PRURITIC		

subjects affected / exposed	5 / 406 (1.23%)	6 / 406 (1.48%)
occurrences (all)	5	6
RASH VESICULAR		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
ROSACEA		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
SEBORRHOEA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
SKIN BURNING SENSATION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
SKIN DEPIGMENTATION		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
SKIN DISORDER		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
SKIN EXFOLIATION		
subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)
occurrences (all)	1	4
SKIN HYPERPIGMENTATION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
SKIN HYPOPIGMENTATION		
subjects affected / exposed	3 / 406 (0.74%)	3 / 406 (0.74%)
occurrences (all)	3	3
SKIN IRRITATION		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
SKIN LESION		
subjects affected / exposed	5 / 406 (1.23%)	7 / 406 (1.72%)
occurrences (all)	5	7
SKIN SENSITISATION		

subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences (all)	1	2	
SKIN STRIAE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
SKIN ULCER			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences (all)	1	2	
SWELLING FACE			
subjects affected / exposed	9 / 406 (2.22%)	3 / 406 (0.74%)	
occurrences (all)	10	4	
URTICARIA			
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)	
occurrences (all)	0	2	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
BLADDER IRRITATION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
BLADDER SPASM			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
CALCULUS BLADDER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
CHRONIC KIDNEY DISEASE			
subjects affected / exposed	3 / 406 (0.74%)	1 / 406 (0.25%)	
occurrences (all)	3	1	
DYSURIA			
subjects affected / exposed	2 / 406 (0.49%)	3 / 406 (0.74%)	
occurrences (all)	2	3	
HAEMATURIA			
subjects affected / exposed	4 / 406 (0.99%)	4 / 406 (0.99%)	
occurrences (all)	5	4	

HYDRONEPHROSIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
NEPHROLITHIASIS		
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	3	2
NOCTURIA		
subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)
occurrences (all)	1	4
POLLAKIURIA		
subjects affected / exposed	5 / 406 (1.23%)	13 / 406 (3.20%)
occurrences (all)	5	14
POLYURIA		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
PROTEINURIA		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
RENAL CYST		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
RENAL IMPAIRMENT		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
RENAL PAIN		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
URINARY INCONTINENCE		
subjects affected / exposed	1 / 406 (0.25%)	5 / 406 (1.23%)
occurrences (all)	1	5
URINARY RETENTION		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
URINARY TRACT DISORDER		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1

URINE ODOUR ABNORMAL subjects affected / exposed occurrences (all)	0 / 406 (0.00%) 0	1 / 406 (0.25%) 1	
Endocrine disorders			
ADRENAL MASS subjects affected / exposed occurrences (all)	1 / 406 (0.25%) 1	0 / 406 (0.00%) 0	
CUSHING'S SYNDROME subjects affected / exposed occurrences (all)	1 / 406 (0.25%) 1	0 / 406 (0.00%) 0	
HYPERTHYROIDISM subjects affected / exposed occurrences (all)	1 / 406 (0.25%) 1	1 / 406 (0.25%) 1	
HYPOTHYROIDISM subjects affected / exposed occurrences (all)	1 / 406 (0.25%) 1	7 / 406 (1.72%) 7	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA subjects affected / exposed occurrences (all)	71 / 406 (17.49%) 79	66 / 406 (16.26%) 95	
ARTHRITIS subjects affected / exposed occurrences (all)	3 / 406 (0.74%) 3	6 / 406 (1.48%) 6	
BACK PAIN subjects affected / exposed occurrences (all)	39 / 406 (9.61%) 43	34 / 406 (8.37%) 39	
BONE LOSS subjects affected / exposed occurrences (all)	1 / 406 (0.25%) 1	0 / 406 (0.00%) 0	
BONE PAIN subjects affected / exposed occurrences (all)	22 / 406 (5.42%) 23	9 / 406 (2.22%) 11	
BURSITIS subjects affected / exposed occurrences (all)	2 / 406 (0.49%) 2	1 / 406 (0.25%) 1	
CHONDROCALCINOSIS			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
CHONDROCALCINOSIS PYROPHOSPHATE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
FISTULA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
FLANK PAIN		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
FOOT DEFORMITY		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
GROIN PAIN		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
HAEMARTHROSIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
INCLUSION BODY MYOSITIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
INTERVERTEBRAL DISC PROTRUSION		
subjects affected / exposed	3 / 406 (0.74%)	0 / 406 (0.00%)
occurrences (all)	3	0
JAW CYST		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
JOINT LOCK		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
JOINT STIFFNESS		

subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)
occurrences (all)	1	4
JOINT SWELLING		
subjects affected / exposed	12 / 406 (2.96%)	8 / 406 (1.97%)
occurrences (all)	12	8
MOBILITY DECREASED		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
MUSCLE SPASMS		
subjects affected / exposed	134 / 406 (33.00%)	14 / 406 (3.45%)
occurrences (all)	179	18
MUSCLE TWITCHING		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
MUSCULAR WEAKNESS		
subjects affected / exposed	4 / 406 (0.99%)	3 / 406 (0.74%)
occurrences (all)	4	5
MUSCULOSKELETAL CHEST PAIN		
subjects affected / exposed	3 / 406 (0.74%)	6 / 406 (1.48%)
occurrences (all)	3	6
MUSCULOSKELETAL DISCOMFORT		
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)
occurrences (all)	3	2
MUSCULOSKELETAL PAIN		
subjects affected / exposed	25 / 406 (6.16%)	22 / 406 (5.42%)
occurrences (all)	30	23
MUSCULOSKELETAL STIFFNESS		
subjects affected / exposed	3 / 406 (0.74%)	3 / 406 (0.74%)
occurrences (all)	3	3
MYALGIA		
subjects affected / exposed	46 / 406 (11.33%)	29 / 406 (7.14%)
occurrences (all)	53	32
NECK MASS		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
NECK PAIN		

subjects affected / exposed	7 / 406 (1.72%)	9 / 406 (2.22%)
occurrences (all)	8	9
OSTEITIS DEFORMANS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
OSTEOARTHRITIS		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
OSTEOPOROSIS		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
PAIN IN EXTREMITY		
subjects affected / exposed	53 / 406 (13.05%)	42 / 406 (10.34%)
occurrences (all)	59	51
PAIN IN JAW		
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)
occurrences (all)	1	3
PERIARTHRITIS		
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)
occurrences (all)	0	3
PLANTAR FASCIITIS		
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	2	2
PLICA SYNDROME		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
RHABDOMYOLYSIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
ROTATOR CUFF SYNDROME		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
SACROILIITIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
SOFT TISSUE SWELLING		

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
SPINAL OSTEOARTHRITIS			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences (all)	2	0	
SPINAL PAIN			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
SYNOVIAL CYST			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
TEMPOROMANDIBULAR JOINT SYNDROME			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
TENDON PAIN			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
TENDONITIS			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences (all)	1	2	
TRIGGER FINGER			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
TRISMUS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
Infections and infestations			
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
ABSCESS			
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)	
occurrences (all)	2	0	
ANAL ABSCESS			

subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
ANAL INFECTION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
ARTHRITIS BACTERIAL		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
BODY TINEA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
BREAST CELLULITIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
BRONCHITIS		
subjects affected / exposed	0 / 406 (0.00%)	4 / 406 (0.99%)
occurrences (all)	0	4
CAMPYLOBACTER INFECTION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
CANDIDA INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
CELLULITIS		
subjects affected / exposed	8 / 406 (1.97%)	9 / 406 (2.22%)
occurrences (all)	10	12
CLOSTRIDIUM DIFFICILE INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
CONJUNCTIVITIS		
subjects affected / exposed	10 / 406 (2.46%)	4 / 406 (0.99%)
occurrences (all)	12	4
CYSTITIS		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
DIABETIC FOOT INFECTION		

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
EAR INFECTION		
subjects affected / exposed	13 / 406 (3.20%)	11 / 406 (2.71%)
occurrences (all)	15	12
ENTERITIS INFECTIOUS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
ENTEROBIASIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	2
EPIDIDYMITIS		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
ESCHERICHIA URINARY TRACT INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
EYE INFECTION		
subjects affected / exposed	3 / 406 (0.74%)	5 / 406 (1.23%)
occurrences (all)	3	5
EYE INFECTION VIRAL		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
EYELID INFECTION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
FOLLICULITIS		
subjects affected / exposed	1 / 406 (0.25%)	10 / 406 (2.46%)
occurrences (all)	1	10
FUNGAL INFECTION		
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)
occurrences (all)	0	3
FUNGAL SKIN INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1

FURUNCLE		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
GASTROENTERITIS		
subjects affected / exposed	2 / 406 (0.49%)	7 / 406 (1.72%)
occurrences (all)	2	8
GASTROENTERITIS NOROVIRUS		
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)
occurrences (all)	3	2
GASTROENTERITIS VIRAL		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
GASTROINTESTINAL VIRAL INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
GENITAL ABSCESS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
GINGIVITIS		
subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)
occurrences (all)	2	1
GROIN ABSCESS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HELICOBACTER INFECTION		
subjects affected / exposed	2 / 406 (0.49%)	2 / 406 (0.49%)
occurrences (all)	2	2
HEPATITIS B		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
HERPES OPHTHALMIC		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HERPES SIMPLEX		

subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	3
HERPES ZOSTER		
subjects affected / exposed	10 / 406 (2.46%)	7 / 406 (1.72%)
occurrences (all)	15	8
HORDEOLUM		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
INFECTED BITE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
INFECTED DERMAL CYST		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
INFECTION		
subjects affected / exposed	6 / 406 (1.48%)	8 / 406 (1.97%)
occurrences (all)	6	8
INFECTIOUS MONONUCLEOSIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
INFECTIVE GLOSSITIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
INFECTIVE KERATITIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
INFLUENZA		
subjects affected / exposed	4 / 406 (0.99%)	8 / 406 (1.97%)
occurrences (all)	4	8
INJECTION SITE INFECTION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
INTERVERTEBRAL DISCITIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	2
KIDNEY INFECTION		

subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	2
LABYRINTHITIS		
subjects affected / exposed	3 / 406 (0.74%)	6 / 406 (1.48%)
occurrences (all)	3	6
LOCALISED INFECTION		
subjects affected / exposed	2 / 406 (0.49%)	4 / 406 (0.99%)
occurrences (all)	2	4
LOWER RESPIRATORY TRACT INFECTION		
subjects affected / exposed	55 / 406 (13.55%)	68 / 406 (16.75%)
occurrences (all)	73	93
LUNG INFECTION		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
LYMPH GLAND INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
LYMPH NODE ABSCESS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
MALARIA		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
NAIL INFECTION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
NASOPHARYNGITIS		
subjects affected / exposed	26 / 406 (6.40%)	32 / 406 (7.88%)
occurrences (all)	34	39
ONYCHOMYCOSIS		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
ORAL CANDIDIASIS		
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)
occurrences (all)	1	3

ORAL FUNGAL INFECTION		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
ORAL HERPES		
subjects affected / exposed	6 / 406 (1.48%)	13 / 406 (3.20%)
occurrences (all)	6	17
ORAL INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	5 / 406 (1.23%)
occurrences (all)	1	5
OTITIS EXTERNA		
subjects affected / exposed	3 / 406 (0.74%)	1 / 406 (0.25%)
occurrences (all)	3	1
OTITIS MEDIA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
OTITIS MEDIA ACUTE		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
PARONYCHIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PAROTITIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
PHARYNGITIS		
subjects affected / exposed	6 / 406 (1.48%)	10 / 406 (2.46%)
occurrences (all)	6	10
PNEUMONIA		
subjects affected / exposed	1 / 406 (0.25%)	5 / 406 (1.23%)
occurrences (all)	1	5
POST PROCEDURAL INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)
occurrences (all)	1	1
RASH PUSTULAR		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1

RESPIRATORY TRACT INFECTION		
subjects affected / exposed	3 / 406 (0.74%)	5 / 406 (1.23%)
occurrences (all)	3	5
RHINITIS		
subjects affected / exposed	3 / 406 (0.74%)	4 / 406 (0.99%)
occurrences (all)	3	4
RHINOVIRUS INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
SEPSIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
SIALOADENITIS		
subjects affected / exposed	0 / 406 (0.00%)	2 / 406 (0.49%)
occurrences (all)	0	2
SINUSITIS		
subjects affected / exposed	4 / 406 (0.99%)	13 / 406 (3.20%)
occurrences (all)	4	14
SKIN CANDIDA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
SKIN INFECTION		
subjects affected / exposed	4 / 406 (0.99%)	2 / 406 (0.49%)
occurrences (all)	4	4
SOFT TISSUE INFECTION		
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)
occurrences (all)	0	3
STAPHYLOCOCCAL INFECTION		
subjects affected / exposed	2 / 406 (0.49%)	0 / 406 (0.00%)
occurrences (all)	2	0
STREPTOCOCCAL INFECTION		
subjects affected / exposed	3 / 406 (0.74%)	0 / 406 (0.00%)
occurrences (all)	3	0
STRONGYLOIDIASIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	2	0

TINEA CRURIS		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
TINEA INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)
occurrences (all)	1	2
TINEA PEDIS		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
TONSILLITIS		
subjects affected / exposed	3 / 406 (0.74%)	2 / 406 (0.49%)
occurrences (all)	3	2
TOOTH ABSCESS		
subjects affected / exposed	4 / 406 (0.99%)	11 / 406 (2.71%)
occurrences (all)	4	11
TOOTH INFECTION		
subjects affected / exposed	5 / 406 (1.23%)	4 / 406 (0.99%)
occurrences (all)	6	6
UPPER RESPIRATORY TRACT INFECTION		
subjects affected / exposed	33 / 406 (8.13%)	39 / 406 (9.61%)
occurrences (all)	36	50
URINARY TRACT INFECTION		
subjects affected / exposed	21 / 406 (5.17%)	32 / 406 (7.88%)
occurrences (all)	29	47
VAGINAL INFECTION		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
VARICELLA		
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)
occurrences (all)	1	0
VIRAL INFECTION		
subjects affected / exposed	9 / 406 (2.22%)	17 / 406 (4.19%)
occurrences (all)	11	18
VIRAL PHARYNGITIS		

subjects affected / exposed	2 / 406 (0.49%)	1 / 406 (0.25%)	
occurrences (all)	2	1	
VIRAL RASH			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 406 (0.49%)	3 / 406 (0.74%)	
occurrences (all)	2	3	
VULVOVAGINAL CANDIDIASIS			
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)	
occurrences (all)	0	3	
WOUND INFECTION			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	1	1	
Metabolism and nutrition disorders			
ALCOHOL INTOLERANCE			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
DECREASED APPETITE			
subjects affected / exposed	18 / 406 (4.43%)	31 / 406 (7.64%)	
occurrences (all)	21	34	
DEHYDRATION			
subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	1	1	
DIABETES MELLITUS			
subjects affected / exposed	1 / 406 (0.25%)	2 / 406 (0.49%)	
occurrences (all)	1	2	
DIABETES MELLITUS INADEQUATE CONTROL			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
FLUID RETENTION			
subjects affected / exposed	16 / 406 (3.94%)	14 / 406 (3.45%)	
occurrences (all)	18	14	
FOLATE DEFICIENCY			

subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
FOOD INTOLERANCE		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
GOUT		
subjects affected / exposed	9 / 406 (2.22%)	12 / 406 (2.96%)
occurrences (all)	12	14
HYPERCHOLESTEROLAEMIA		
subjects affected / exposed	0 / 406 (0.00%)	5 / 406 (1.23%)
occurrences (all)	0	5
HYPERKALAEMIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	2
HYPERLIPIDAEMIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HYPERNATRAEMIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HYPERTRIGLYCERIDAEMIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HYPOCALCAEMIA		
subjects affected / exposed	6 / 406 (1.48%)	3 / 406 (0.74%)
occurrences (all)	6	7
HYPOGLYCAEMIA		
subjects affected / exposed	1 / 406 (0.25%)	3 / 406 (0.74%)
occurrences (all)	1	4
HYPOKALAEMIA		
subjects affected / exposed	4 / 406 (0.99%)	2 / 406 (0.49%)
occurrences (all)	8	2
HYPOMAGNESAEMIA		
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)
occurrences (all)	0	1
HYPOPHOSPHATAEMIA		

subjects affected / exposed	1 / 406 (0.25%)	1 / 406 (0.25%)	
occurrences (all)	14	1	
INCREASED APPETITE			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
IRON DEFICIENCY			
subjects affected / exposed	0 / 406 (0.00%)	3 / 406 (0.74%)	
occurrences (all)	0	3	
TETANY			
subjects affected / exposed	1 / 406 (0.25%)	0 / 406 (0.00%)	
occurrences (all)	1	0	
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
TYPE 2 DIABETES MELLITUS			
subjects affected / exposed	0 / 406 (0.00%)	1 / 406 (0.25%)	
occurrences (all)	0	1	
VITAMIN D DEFICIENCY			
subjects affected / exposed	1 / 406 (0.25%)	4 / 406 (0.99%)	
occurrences (all)	1	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 June 2016	The protocol was updated as regarding guidance on management of pleural effusions and the addition of concerns around pulmonary arterial hypertension. The requirement for bone marrow trephine was removed. For laboratory evaluations, LDH was changed to optional, lymphocyte count added and only one test for either AST or ALT was made acceptable. The definition of serious adverse events was updated to include new malignancies and CML disease progression. The section on study drug dose escalation was updated. Drug storage conditions and contraindications were updated to reflect the SmPC. Amendments also allowed GCSF to be given as a concomitant medication and advice regarding QT prolongation with TKIs was updated. The contact details for trials team, sponsor and central laboratory were updated.
12 December 2016	The protocol was updated to allow the use of generic imatinib, to remove the requirement for bone marrow aspirate samples, to correct SAE definitions and other typographical errors and inconsistencies.

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.

The additional endpoint of broad comparative costs between the regimens as described in the protocol, was not analysed at the end of study as there was no beneficial reason to do so when imatinib became generic in Dec 2016 at vastly reduced cost.

Notes: