Clinical trial results:
A Phase 3 Randomized, Double-Blind Study Assessing the Efficacy and Safety of PF-06438179 and Infliximab in Combination With Methotrexate in Subjects With Moderately to Severely Active Rheumatoid Arthritis Who Have Had an Inadequate Response to Methotrexate

Summary

EudraCT number	2013-004148-49
Trial protocol	LT CZ GB HU DE PL BG FR
Global end of trial date	01 June 2017

Results information

Result version number	v1 (current)
This version publication date	02 June 2018
First version publication date	12 July 2017

Trial information

Trial identification

Sponsor protocol code	B5371002

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 November 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 June 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to compare the efficacy between PF-06438179 and infliximab-EU in subjects with moderately to severely active RA who are treated with infliximab in combination with methotrexate.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 August 2014
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	Australia: 4
Country: Number of subjects enrolled	Bosnia and Herzegovina: 57
Country: Number of subjects enrolled	Brazil: 3
Country: Number of subjects enrolled	Bulgaria: 28
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Czech Republic: 73
Country: Number of subjects enrolled	Georgia: 45
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Guatemala: 14
Country: Number of subjects enrolled	Hungary: 5
Country: Number of subjects enrolled	Japan: 47
Country: Number of subjects enrolled	Jordan: 2
Country: Number of subjects enrolled	Korea, Republic of: 9
Country: Number of subjects enrolled	Lithuania: 15
Country: Number of subjects enrolled	Mexico: 12
Country: Number of subjects enrolled	Peru: 15
Country: Number of subjects enrolled	Philippines: 34
Country: Number of subjects enrolled	Poland: 15
Country: Number of subjects enrolled	Romania: 4

Country: Number of subjects enrolled	Russian Federation: 52
Country: Number of subjects enrolled	Serbia: 13
Country: Number of subjects enrolled	South Africa: 4
Country: Number of subjects enrolled	Tunisia: 1
Country: Number of subjects enrolled	Ukraine: 97
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	United States: 82
Worldwide total number of subjects	650
EEA total number of subjects	154

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)	518
From 65 to 84 years	131
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 1603 subjects were screened after signing an informed consent form, of whom 650 subjects were randomized to receive study treatment. One (1) subject in the PF-06438179 arm was screened and randomized by 2 different study site personnel, and no data were collected for the subjects second randomization.

Period 1

Period 1 title	Period 1: First dose-Week 30 (pre-dose)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	PF-06438179

Arm description:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Arm type	Experimental
Investigational medicinal product name	PF-06438179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Arm title	Infliximab-EU Remicade (INX)

Arm description:

Subjects received intravenous infusions of INX at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2), when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Arm type	Experimental
Investigational medicinal product name	Infliximab-EU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusions of INX at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2), when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Number of subjects in period 1	PF-06438179	Infliximab-EU Remicade (INX)
Started	324	326
Received treatment	323	326
Completed	280	286
Not completed	44	40
Adverse event, serious fatal	2	2
Consent withdrawn by subject	11	9
Adverse event, non-fatal	18	20
Randomized but not treated	1	-
Non-compliance with study treatment	1	-
Pregnancy	2	-
Unspecified	4	-
Lost to follow-up	-	1
Protocol deviation	5	1
Insufficient clinical response	-	7

Period 2

Period 2 title	Period 2: Week30 dosing-Week54(pre-dose)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	PF-06438179

Arm description:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Arm type	Experimental
Investigational medicinal product name	PF-06438179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Arm title	Infliximab-EU Remicade (INX)

Arm description:

Subjects received intravenous infusions of INX at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2), when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Arm type	Active comparator
Investigational medicinal product name	Infliximab-EU
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusions of INX at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2), when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Number of subjects in period 2	PF-06438179	Infliximab-EU Remicade (INX)
Started	423	143
Completed	380	126
Not completed	43	17
Adverse event, serious fatal	1	-
Consent withdrawn by subject	6	4
Adverse event, non-fatal	22	9
Non-compliance with study treatment	1	-
Unspecified	3	-
Lost to follow-up	1	1
Insufficient clinical response	9	3

Period 3

Period 3 title	Period 3: Week 54 dosing-Week 78 visit
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	PF-06438179

Arm description:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Arm type	Experimental
Investigational medicinal product name	PF-06438179
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Number of subjects in period 3[1]	PF-06438179
Started	505
Completed	474
Not completed	31
Consent withdrawn by subject	9
Adverse event, non-fatal	14
Non-compliance with study treatment	1
Unspecified	4
Insufficient clinical response	3

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Subjects in Infliximab-EU arm were switched to PF-06438179 arm in preceding periods; and in Period 3 all subjects were switched to PF-06438179 arm.

Baseline characteristics

Reporting groups	
Reporting group title	PF-06438179

Reporting group description:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Reporting group title	Infliximab-EU Remicade (INX)

Reporting group description:

Subjects received intravenous infusions of INX at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2), when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Reporting group values	PF-06438179	Infliximab-EU Remicade (INX)	Total
Number of subjects	324	326	650
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	259	259	518
From 65-84 years	64	67	131
85 years and over	1	0	1
Age Continuous Units: years			
arithmetic mean	52.8	52.8	
standard deviation	± 13.3	± 12.9	-
Gender, Male/Female Units: Subjects			
Female	258	264	522
Male	66	62	128

Subject analysis sets

Subject analysis set title	Period 1: PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects were scheduled to receive intravenous infusions of PF-06438179 at a dose of 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessment. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks.

Subject analysis set title	Period 1: Infliximab-EU Remicade (INX)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects were scheduled to receive intravenous infusions of INX at a dose of 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessment. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks.

Subject analysis set title	Period 2: PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects randomized to receive intravenous infusions of PF-06438179 in Period 1 were scheduled to receive PF-06438179 in Period 2 at a dose of 3 mg/kg or 5 mg/kg on Weeks 30, 38 and 46. Period 2 ended with the completion of the Week 54 pre-dose assessments.

Subject analysis set title	Period 2: INX/INX
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects randomized to receive intravenous infusions of INX in Period 1 were scheduled to receive INX in Period 2 at a dose of 3 mg/kg or 5 mg/kg on Weeks 30, 38 and 46. Period 2 ended with the completion of the Week 54 pre-dose assessments.

Subject analysis set title	Period 2: INX/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects randomized to receive intravenous infusions of INX in Period 1 were scheduled to receive PF-06438179 in Period 2 at a dose of 3 mg/kg or 5 mg/kg on Weeks 30, 38 and 46. Period 2 ended with the completion of the Week 54 pre-dose assessments.

Subject analysis set title	Period 3: PF-06438179/PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of PF-06438179 in Period 1 and Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 3: INX/INX/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of INX in Period 1 and Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 3: INX/PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of INX in Period 1 and PF-06438179 in Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 3: INX/INX/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of INX in Period 1 and Period 2. In Period 3 they were scheduled

to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 3: INX/PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of INX in Period 1 and PF-06438179 in Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 1: PF-06438179
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects were scheduled to receive intravenous infusions of PF-06438179 at a dose of 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessment. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks.

Subject analysis set title	Period 3: PF-06438179/PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of PF-06438179 in Period 1 and Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Reporting group values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)	Period 2: PF-06438179/PF-06438179
Number of subjects	324	326	280
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	52.8	52.8	52.8
standard deviation	± 13.3	± 12.9	± 12.9
Gender, Male/Female Units: Subjects			
Female Male			

Reporting group values	Period 2: INX/INX	Period 2: INX/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179
Number of subjects	143	143	253
Age categorical Units: Subjects			
In utero			

Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	53.8	51.6	52.4
standard deviation	± 12.7	± 12.9	± 12.8
Gender, Male/Female Units: Subjects			
Female			
Male			

Reporting group values	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	Period 3: INX/INX/PF-06438179
Number of subjects	126	126	126
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	53.5	51.3	53.5
standard deviation	± 12.4	± 12.6	± 12.4
Gender, Male/Female Units: Subjects			
Female			
Male			

Reporting group values	Period 3: INX/PF-06438179/PF-06438179	Period 1: PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179
Number of subjects	126	323	253
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks)			

Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	51.3	52.8	52.4
standard deviation	± 12.6	± 13.3	± 12.8
Gender, Male/Female Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	PF-06438179

Reporting group description:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Reporting group title	Infliximab-EU Remicade (INX)

Reporting group description:

Subjects received intravenous infusions of INX at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2), when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Reporting group title	PF-06438179

Reporting group description:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Reporting group title	Infliximab-EU Remicade (INX)

Reporting group description:

Subjects received intravenous infusions of INX at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2), when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Reporting group title	PF-06438179

Reporting group description:

Subjects received intravenous infusions of PF-06438179 at 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessments. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks. Subjects initially randomized to PF-06438179 continued to blindly receive PF-06438179 in Period 2. A second randomization was blindly performed prior to dosing at Week 30 (at the beginning of Period 2, when subjects initially randomized to INX were re-randomized in a 1:1 ratio, with 50% of the subjects switching to PF-06438179 and the other 50% of subjects remaining on the INX arm. Period 3 started with dosing at Week 54 where all subjects began open label treatment with PF-06438179.

Subject analysis set title	Period 1: PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects were scheduled to receive intravenous infusions of PF-06438179 at a dose of 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessment. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks.

Subject analysis set title	Period 1: Infliximab-EU Remicade (INX)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects were scheduled to receive intravenous infusions of INX at a dose of 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessment. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks.

Subject analysis set title	Period 2: PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects randomized to receive intravenous infusions of PF-06438179 in Period 1 were scheduled to receive PF-06438179 in Period 2 at a dose of 3 mg/kg or 5 mg/kg on Weeks 30, 38 and 46. Period 2 ended with the completion of the Week 54 pre-dose assessments.

Subject analysis set title	Period 2: INX/INX
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects randomized to receive intravenous infusions of INX in Period 1 were scheduled to receive INX in Period 2 at a dose of 3 mg/kg or 5 mg/kg on Weeks 30, 38 and 46. Period 2 ended with the completion of the Week 54 pre-dose assessments.

Subject analysis set title	Period 2: INX/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects randomized to receive intravenous infusions of INX in Period 1 were scheduled to receive PF-06438179 in Period 2 at a dose of 3 mg/kg or 5 mg/kg on Weeks 30, 38 and 46. Period 2 ended with the completion of the Week 54 pre-dose assessments.

Subject analysis set title	Period 3: PF-06438179/PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of PF-06438179 in Period 1 and Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 3: INX/INX/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of INX in Period 1 and Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 3: INX/PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of INX in Period 1 and PF-06438179 in Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 3: INX/INX/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of INX in Period 1 and Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 3: INX/PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of INX in Period 1 and PF-06438179 in Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Subject analysis set title	Period 1: PF-06438179
Subject analysis set type	Safety analysis

Subject analysis set description:

Subjects were scheduled to receive intravenous infusions of PF-06438179 at a dose of 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessment. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks.

Subject analysis set title	Period 3: PF-06438179/PF-06438179/PF-06438179
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects received intravenous infusions of PF-06438179 in Period 1 and Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Primary: Number of Subjects With an American College of Rheumatology 20% (ACR20) Response at Week 14: Period 1

End point title	Number of Subjects With an American College of Rheumatology 20% (ACR20) Response at Week 14: Period 1

End point description:

ACR20 response: greater than or equal to (>=) 20 percent (%) improvement in tender joint count (TJC); >= 20% improvement in swollen joint count (SJC); and >= 20% improvement in at least 3 of 5 remaining ACR core measures: subject assessment of pain; subject global assessment of disease activity (PGA); physician global assessment of disease activity; self-assessed disability (health assessment questionnaire-disability index [HAQ-DI]); and C-Reactive Protein (CRP). The ITT Population was defined as all subjects who were randomized to study treatment.

End point type	Primary

End point timeframe:

Week 14

End point values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	324	326		
Units: subjects	198	207		

Statistical analyses

Statistical analysis title	PF-06438179 vs Infliximab-EU

Statistical analysis description:

Score statistic method

Comparison groups	Period 1: PF-06438179 v Period 1: Infliximab-EU Remicade (INX)

Number of subjects included in analysis	650
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Proportion Difference
Point estimate	-2.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.92
upper limit	5.11

Statistical analysis title	PF-06438179 vs Infliximab-EU
Statistical analysis description:	
Score statistic method	
Comparison groups	Period 1: PF-06438179 v Period 1: Infliximab-EU Remicade (INX)
Number of subjects included in analysis	650
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Proportion Difference
Point estimate	-2.39
Confidence interval	
level	90 %
sides	2-sided
lower limit	-8.75
upper limit	4.02

Secondary: Number of Subjects With an American College of Rheumatology 20% (ACR20) Response at Week 2, 4, 6, 12, 22 and 30 (pre-dose): Period 1

End point title	Number of Subjects With an American College of Rheumatology 20% (ACR20) Response at Week 2, 4, 6, 12, 22 and 30 (pre-dose): Period 1

End point description:

ACR20 response: >=20% improvement in tender joint count; >=20% improvement in swollen joint count; and >=20% improvement in at least 3 of 5 remaining ACR core measures: subject assessment of pain; subject global assessment of disease activity; physician global assessment of disease activity; HAQ-DI and CRP. The ITT Population was defined as all subjects who were randomized to study treatment.

End point type	Secondary

End point timeframe:

Week 2, 4, 6, 12, 22 and 30 (pre-dose)

End point values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	324	326		
Units: subjects				
Week 2	105	121		
Week 4	170	190		
Week 6	187	201		
Week 12	210	214		
week 22	205	213		
Week 30 (pre-dose)	197	209		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With an American College of Rheumatology 20% (ACR20) Response at Week 38, 46 and 54 (pre-dose): Period 2

End point title	Number of Subjects With an American College of Rheumatology 20% (ACR20) Response at Week 38, 46 and 54 (pre-dose): Period 2

End point description:

ACR20 response: >=20% improvement in tender joint count; >=20% improvement in swollen joint count; and >=20% improvement in at least 3 of 5 remaining ACR core measures: subject assessment of pain; subject global assessment of disease activity; physician global assessment of disease activity; HAQ-DI and CRP. The ITT Population was defined as all subjects who were randomized to study treatment.

End point type	Secondary

End point timeframe:

Week 38, 46 and 54 (pre-dose)

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	280	143	143	
Units: subjects				
Week 38	206	101	110	
Week 46	199	98	99	
Week 54 (pre-dose)	199	92	101	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With an American College of Rheumatology 20% (ACR20) Response at Week 62, 70 and 78: Period 3

End point title	Number of Subjects With an American College of Rheumatology 20% (ACR20) Response at Week 62, 70 and 78: Period 3

End point description:

ACR20 response: >=20% improvement in tender joint count; >=20% improvement in swollen joint count; and >=20% improvement in at least 3 of 5 remaining ACR core measures: subject assessment of pain; subject global assessment of disease activity; physician global assessment of disease activity; HAQ-DI and CRP. The ITT population included all subjects enrolled and treated with at least 1 dose of study treatment in Period 3.

End point type	Secondary

End point timeframe:

Week 62, 70 and 78

End point values	Period 3: PF-06438179/PF-06438179/PF-06438179	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	253	126	126	
Units: subjects				
Week 62	199	89	103	
Week 70	199	87	98	
Week 78	192	86	98	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With an American College of Rheumatology 50% (ACR50) and ACR 70% Response at Week 2, 4, 6, 12, 14, 22 and 30 (pre-dose): Period 1

End point title	Number of Subjects With an American College of Rheumatology 50% (ACR50) and ACR 70% Response at Week 2, 4, 6, 12, 14, 22 and 30 (pre-dose): Period 1

End point description:

ACR50 response: >=50% improvement in tender joint count, >=50% improvement in swollen joint count improvement and >=50% in at least 3 of 5 remaining ACR core measures: subject assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, HAQ-DI and CRP. ACR70 response: >=70% improvement in tender joint count, >=70% improvement in swollen joint count improvement and >=70% in at least 3 of 5 remaining ACR core measures: subject assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, HAQ-DI and CRP. The ITT Population was defined as all subjects who were randomized to study treatment.

End point type	Secondary

End point timeframe:

Week 2, 4, 6, 12, 14, 22 and 30 (pre-dose)

End point values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	324	326		
Units: subjects				
ACR50 (Week 2)	24	24		
ACR50 (Week 4)	72	59		
ACR50 (Week 6)	88	80		
ACR50 (Week 12)	95	101		
ACR50 (Week 14)	116	108		
ACR50 (Week 22)	126	116		
ACR50 (Week 30, pre-dose)	125	132		
ACR70 (Week 2)	6	6		
ACR70 (Week 4)	22	13		
ACR70 (Week 6)	33	16		
ACR70 (Week 12)	46	40		
ACR70 (Week 14)	56	33		
ACR70 (Week 22)	56	45		
ACR70 (Week 30, pre-dose)	67	58		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With an American College of Rheumatology 50% (ACR50) and ACR 70% Response at Week 38, 46 and 54 (pre-dose): Period 2

End point title	Number of Subjects With an American College of Rheumatology 50% (ACR50) and ACR 70% Response at Week 38, 46 and 54 (pre-dose): Period 2

End point description:

ACR50 response: >=50% improvement in tender joint count, >=50% improvement in swollen joint count improvement and >=50% in at least 3 of 5 remaining ACR core measures: subject assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, HAQ-DI and CRP. ACR70 response: >=70% improvement in tender joint count, >=70% improvement in swollen joint count improvement and >=70% in at least 3 of 5 remaining ACR core measures: subject assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, HAQ-DI and CRP. The ITT Population was defined as all subjects who were randomized to study treatment.

End point type	Secondary

End point timeframe:

Week 38, 46 and 54 (pre-dose)

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	280	143	143	
Units: subjects				
ACR50 (Week 38)	132	58	75	
ACR50 (Week 46)	135	55	63	
ACR50 (Week 54, pre-dose)	135	61	65	
ACR70 (Week 38)	77	33	38	
ACR70 (Week 46)	75	33	33	
ACR70 (Week 54, pre-dose)	82	33	35	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With an American College of Rheumatology 50% (ACR50) and ACR 70% Response at Week 62, 70 and 78: Period 3

End point title	Number of Subjects With an American College of Rheumatology 50% (ACR50) and ACR 70% Response at Week 62, 70 and 78: Period 3

End point description:

ACR50 response: >=50% improvement in tender joint count, >=50% improvement in swollen joint count improvement and >=50% in at least 3 of 5 remaining ACR core measures: subject assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, HAQ-DI and CRP. ACR70 response: >=70% improvement in tender joint count, >=70% improvement in swollen joint count improvement and >=70% in at least 3 of 5 remaining ACR core measures: subject assessment of pain, subject global assessment of disease activity, physician global assessment of disease activity, HAQ-DI and CRP. The ITT population included all subjects enrolled and treated with at least 1 dose of study treatment in Period 3.

End point type	Secondary

End point timeframe:

Week 62, 70 and 78

End point values	Period 3: PF-06438179/PF-06438179/PF-06438179	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	253	126	126	
Units: subjects				
ACR50 (Week 62)	132	59	71	
ACR50 (Week 70)	142	61	67	
ACR50 (Week 78)	150	57	73	
ACR70 (Week 62)	88	31	41	
ACR70 (Week 70)	92	35	44	
ACR70 (Week 78)	98	33	44	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Disease Activity Score-CRP (4 Variables) (DAS28-4 [CRP]) and HAQ-DI at Week 2, 4, 6, 12, 14, 22 and 30: Period 1

End point title	Change From Baseline in Disease Activity Score-CRP (4 Variables) (DAS28-4 [CRP]) and HAQ-DI at Week 2, 4, 6, 12, 14, 22 and 30: Period 1

End point description:

DAS28: measure of disease activity in subjects. DAS28-4 (CRP): calculated from SJC, TJC, CRP and PGA (participant rated disease activity on visual analogue scale [VAS] from 0-100 millimetres [mm]; high score=worse health). Total score range of DAS28-4 (CRP): 0(no) to 9.4(extreme disease activity), higher score=more disease activity (less than [<] 2.6=remission, <3.2=low disease activity, >=3.2-5.1=moderate disease activity and >5.1=high disease activity). HAQ-DI assess degree of difficulty subject experienced in 8 domain of daily activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip and other activities. Each item scored on 4-point scale ranging from 0-3(0=no difficulty; 3=extreme difficulty). Overall score: sum of domain scores/number of domains answered. Total possible score range 0(least difficulty) to 3(extreme difficulty): high score=more difficulty in performing daily living activities. ITT Population. n=subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 2, 4, 6, 12, 14, 22 and 30

End point values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	324	326		
Units: units on a scale				
arithmetic mean (standard deviation)				
DAS28-CRP (Baseline; n= 321, 325)	5.950 (± 0.9577)	5.983 (± 0.9210)		
DAS28-CRP (Change at Week 2; n= 318, 324)	-1.213 (± 0.9280)	-1.241 (± 0.8879)		
DAS28-CRP (Change at Week 4; n= 312, 315)	-1.596 (± 1.1259)	-1.605 (± 1.0881)		
DAS28-CRP (Change at Week 6; n= 312, 319)	-1.710 (± 1.1959)	-1.750 (± 1.0885)		
DAS28-CRP (Change at Week 12; n= 310, 316)	-1.898 (± 1.3516)	-1.885 (± 1.2142)		
DAS28-CRP (Change at Week 14; n= 310, 314)	-1.901 (± 1.4125)	-1.827 (± 1.3019)		
DAS28-CRP (Change at Week 22; n= 301, 307)	-2.005 (± 1.4236)	-2.002 (± 1.2972)		
DAS28-CRP (Change at Week 30; n= 292, 297)	-2.140 (± 1.4197)	-2.117 (± 1.2738)		

HAQ-DI (Baseline; n= 321, 325)	1.623 (± 0.6485)	1.586 (± 0.6490)		
HAQ-DI (Change at Week 2; n= 320, 324)	-0.317 (± 0.4100)	-0.328 (± 0.4370)		
HAQ-DI (Change at Week 4; n= 317, 321)	-0.472 (± 0.4728)	-0.477 (± 0.4861)		
HAQ-DI (Change at Week 6; n= 314, 320)	-0.496 (± 0.5505)	-0.520 (± 0.5022)		
HAQ-DI (Change at Week 12; n= 311, 318)	-0.535 (± 0.5795)	-0.524 (± 0.5857)		
HAQ-DI (Change at Week 14; n= 311, 316)	-0.572 (± 0.5910)	-0.531 (± 0.5876)		
HAQ-DI (Change at Week 22; n= 301, 311)	-0.588 (± 0.6061)	-0.569 (± 0.5958)		
HAQ-DI (Change at Week 30; n= 294, 298)	-0.621 (± 0.6484)	-0.612 (± 0.6546)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Disease Activity Score-CRP (4 Variables) (DAS28-4 [CRP]) and HAQ-DI at Week 38, 46 and 54: Period 2

End point title	Change From Baseline in Disease Activity Score-CRP (4 Variables) (DAS28-4 [CRP]) and HAQ-DI at Week 38, 46 and 54: Period 2

End point description:

DAS28: measure of disease activity in subjects. DAS28-4 (CRP): calculated from SJC, TJC, CRP and PGA (participant rated disease activity on VAS from 0-100 mm; high score =worse health). Total score range of DAS28-4 (CRP): 0(no) to 9.4(extreme disease activity), higher score=more disease activity (<2.6=remission, <3.2=low disease activity, >=3.2-5.1=moderate disease activity and >5.1=high disease activity). HAQ-DI assess degree of difficulty subject experienced in 8 domain of daily activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip and other activities. Each item scored on 4-point scale ranging from 0-3(0=no difficulty; 3=extreme difficulty). Overall score: sum of domain scores/number of domains answered. Total possible score range 0(least difficulty) to 3(extreme difficulty): high score=more difficulty in performing daily living activities. ITT Population. N=subjects evaluable for this outcome measure, n=subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 30 pre-dose), Week 38, 46 and 54

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	278	142	141	
Units: units on a scale				
arithmetic mean (standard deviation)				
DAS28-CRP (Baseline; n= 278, 142, 141)	3.765 (± 1.4629)	3.819 (± 1.3624)	3.781 (± 1.2547)	
DAS28-CRP (Change at Week 38; n= 276, 141, 140)	-0.181 (± 0.9574)	0.036 (± 0.8686)	-0.059 (± 0.8756)	
DAS28-CRP (Change at Week 46; n= 266, 138, 133)	-0.228 (± 1.0453)	0.048 (± 1.2584)	-0.017 (± 1.0692)	

DAS28-CRP (Change at Week 54; n= 256, 129, 128)	-0.275 (± 1.1338)	-0.109 (± 1.1801)	-0.057 (± 1.2339)	
HAQ-DI (Change at Baseline; n= 278, 142, 141)	0.978 (± 0.7042)	0.913 (± 0.6634)	0.951 (± 0.6481)	
HAQ-DI (Change at Week 38; n= 277, 141, 141)	-0.019 (± 0.3328)	0.019 (± 0.2889)	0.007 (± 0.3688)	
HAQ-DI (Change at Week 46; n= 269, 138, 133)	-0.043 (± 0.3774)	0.014 (± 0.3823)	0.035 (± 0.4325)	
HAQ-DI (Change at Week 54; n= 259, 130, 129)	-0.026 (± 0.4407)	0.017 (± 0.4399)	-0.044 (± 0.3881)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Disease Activity Score-CRP (4 Variables) (DAS28-4 [CRP]) and HAQ-DI at Week 62, 70 and 78: Period 3

End point title	Change From Baseline in Disease Activity Score-CRP (4 Variables) (DAS28-4 [CRP]) and HAQ-DI at Week 62, 70 and 78: Period 3

End point description:

DAS28: measure of disease activity in subjects. DAS28-4 (CRP): calculated from SJC, TJC, CRP and PGA (participant rated disease activity on VAS from 0-100 mm; high score =worse health). Total score range of DAS28-4 (CRP): 0(no) to 9.4(extreme disease activity), higher score=more disease activity (<2.6=remission, <3.2=low disease activity, >=3.2-5.1=moderate disease activity and >5.1=high disease activity). HAQ-DI assess degree of difficulty subject experienced in 8 domain of daily activities: dressing and grooming, arising, eating, walking, hygiene, reach, grip and other activities. Each item scored on 4-point scale ranging from 0-3(0=no difficulty; 3=extreme difficulty). Overall score: sum of domain scores/number of domains answered. Total possible score range 0(least difficulty) to 3(extreme difficulty): high score=more difficulty in performing daily living activities. ITT Population. N=subjects evaluable for this outcome measure, n=subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 54 pre-dose), Week 62, 70 and 78

End point values	Period 3: PF-06438179/PF-06438179/PF-06438179	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	249	123	126	
Units: units on a scale				
arithmetic mean (standard deviation)				
DAS28-CRP (Baseline; n= 249, 123, 124)	3.386 (± 1.3229)	3.561 (± 1.3123)	3.594 (± 1.2572)	
DAS28-CRP (Change at Week 62; n= 249, 123, 124)	-0.072 (± 0.9150)	-0.004 (± 0.8190)	-0.154 (± 0.6840)	
DAS28-CRP (Change at Week 70; n= 244, 119, 121)	-0.157 (± 0.9502)	-0.168 (± 0.8421)	-0.162 (± 0.7970)	
DAS28-CRP (Change at Week 78; n= 239, 114, 118)	-0.236 (± 1.0361)	-0.269 (± 0.9759)	-0.215 (± 1.0584)	
HAQ-DI (Baseline; n= 249, 123, 124)	0.905 (± 0.7050)	0.893 (± 0.6691)	0.883 (± 0.6109)	

HAQ-DI (Change at Week 62; n= 249, 123, 124)	-0.024 (± 0.3126)	0.021 (± 0.2989)	0.008 (± 0.2942)	
HAQ-DI (Change at Week 70; n= 244, 119, 121)	-0.046 (± 0.3502)	-0.027 (± 0.2758)	0.030 (± 0.2950)	
HAQ-DI (Change at Week 78; n= 239, 114, 118)	-0.079 (± 0.3869)	-0.022 (± 0.3521)	0.001 (± 0.3800)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Achieving American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) and Disease Activity Score (DAS <2.6) Remission: Period 1

End point title	Number of Subjects Achieving American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) and Disease Activity Score (DAS <2.6) Remission: Period 1

End point description:

ACR/EULAR remission was considered if the scores on tender joint count, swollen joint count, hs-CRP, and patient's global assessment of arthritis (PGA) all were less than or equal to (=<) 1 or the score on the simplified disease activity index (SDAI) was =<3.3. SDAI: sum of number of tender and swollen joint count (using 28 joints), PGA, physician global assessment, and CRP (mg/dL). PGA was assessed on 10 mm VAS ranging from 0 (very well) to 10 (very poor), where higher scores=worse health condition. Physician global assessment was recorded on 10 mm VAS ranging from 0 (very well) to 10 (very poor), where higher scores=more disease activity. DAS28 calculated from number of swollen joints and painful joints using the 28 joints count, CRP and PGA using a 10 mm-VAS (from 0 [very well] to 10 [very poor], where higher scores=worse health condition. DAS28 <3.2: low disease activity, DAS28<2.6: remission. The ITT Population was defined as all subjects who were randomized to study treatment.

End point type	Secondary

End point timeframe:

Week 2, 4, 6, 12, 14, 22 and 30 (pre-dose)

End point values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	324	326		
Units: subjects				
ACR/EULAR remission (Week 2)	2	3		
ACR/EULAR remission (Week 4)	10	11		
ACR/EULAR remission (Week 6)	12	10		
ACR/EULAR remission (Week 12)	28	17		
ACR/EULAR remission (Week 14)	27	22		
ACR/EULAR remission (Week 22)	25	20		
ACR/EULAR remission (Week 30, pre-dose)	30	23		
DAS remission (Week 2)	9	17		
DAS remission (Week 4)	28	32		
DAS remission (Week 6)	40	35		
DAS remission (Week 12)	52	44		

DAS remission (Week 14)	53	43		
DAS remission (Week 22)	58	50		
DAS remission (Week 30, pre-dose)	62	54		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Achieving American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) and Disease Activity Score (DAS <2.6) Remission: Period 2

End point title	Number of Subjects Achieving American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) and Disease Activity Score (DAS <2.6) Remission: Period 2

End point description:

ACR/EULAR remission was considered if the scores on tender joint count, swollen joint count, hs-CRP, and PGA all were =<1 or the score on the SDAI was =<3.3. SDAI: sum of number of tender and swollen joint count (using 28 joints), PGA, physician global assessment, and CRP (mg/dL). PGA was assessed on 10 mm VAS ranging from 0 (very well) to 10 (very poor), where higher scores=worse health condition. Physician global assessment was recorded on 10 mm VAS ranging from 0 (very well) to 10 (very poor), where higher scores=more disease activity. DAS28 calculated from number of swollen joints and painful joints using the 28 joints count, CRP and PGA using a 10 mm-VAS (from 0 [very well] to 10 [very poor], where higher scores=worse health condition. DAS28 <3.2: low disease activity, DAS28<2.6: remission. The ITT Population was defined as all subjects who were randomized to study treatment.

End point type	Secondary

End point timeframe:

Week 38, 46 and 54 (pre-dose)

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	280	143	143	
Units: subjects				
ACR/EULAR remission (Week 38)	29	15	8	
ACR/EULAR remission (Week 46)	39	15	7	
ACR/EULAR remission (Week 54, pre-dose)	42	18	13	
DAS remission (Week 38)	74	26	25	
DAS remission (Week 46)	76	30	21	
DAS remission (Week 54, pre-dose)	79	33	29	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Achieving American College of

Rheumatology/European League Against Rheumatism (ACR/EULAR) and Disease Activity Score (DAS <2.6) Remission: Period 3

End point title	Number of Subjects Achieving American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) and Disease Activity Score (DAS <2.6) Remission: Period 3

End point description:

ACR/EULAR remission was considered if the scores on tender joint count, swollen joint count, hs-CRP, and PGA all were =<1 or the score on the SDAI was =<3.3. SDAI: sum of number of tender and swollen joint count (using 28 joints), PGA, physician global assessment, and CRP (mg/dL). PGA was assessed on 10 mm VAS ranging from 0 (very well) to 10 (very poor), where higher scores=worse health condition. Physician global assessment was recorded on 10 mm VAS ranging from 0 (very well) to 10 (very poor), where higher scores=more disease activity. DAS28 calculated from number of swollen joints and painful joints using the 28 joints count, CRP and PGA using a 10 mm-VAS (from 0 [very well] to 10 [very poor], where higher scores=worse health condition. DAS28 <3.2: low disease activity, DAS28<2.6: remission. The ITT Population was defined as all subjects who were randomized to study treatment.

End point type	Secondary

End point timeframe:

Week 62, 70 and 78

End point values	Period 3: PF-06438179/PF-06438179/PF-06438179	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	253	126	126	
Units: subjects				
ACR/EULAR remission (Week 62)	46	19	20	
ACR/EULAR remission (Week 70)	50	18	19	
ACR/EULAR remission (Week 78)	57	19	18	
DAS remission (Week 62)	85	33	34	
DAS remission (Week 70)	82	40	34	
DAS remission (Week 78)	94	39	41	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With European League Against Rheumatism (EULAR) Response: Period 1

End point title	Number of Subjects With European League Against Rheumatism (EULAR) Response: Period 1

End point description:

EULAR response was based on DAS28 EULAR response criteria defined as Good response = DAS28 change >1.2 with DAS28 =<3.2; Moderate response = DAS28 change >0.6-=<1.2 with DAS28 >3.2-5.1; no-response = DAS28 change =<0.6 with DAS28 >5.1. The ITT Population was defined as all subjects who were randomized to study treatment. Here, "n" signifies number of subjects who were evaluable for the specified categories, for each arm respectively.

End point type	Secondary

End point timeframe:

Week 2, 4, 6, 12, 14, 22, 30 (pre-dose)

End point values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	324	326		
Units: subjects				
Week 2 (good response; n= 317, 324)	24	34		
Week 2 (moderate response; n= 317, 324)	172	161		
Week 2 (no response; n= 317, 324)	121	129		
Week 4 (good response; n= 312, 315)	61	56		
Week 4 (moderate response; n= 312, 315)	162	172		
Week 4 (no response; n= 312, 315)	89	87		
Week 6 (good response; n= 312, 319)	65	64		
Week 6 (moderate response; n= 312, 319)	168	181		
Week 6 (no response; n= 312, 319)	79	74		
Week 12 (good response; n= 310, 316)	90	88		
Week 12 (moderate response; n= 310, 316)	149	162		
Week 12 (no response; n= 310, 316)	71	66		
Week 14 (good response; n= 310, 314)	97	82		
Week 14 (moderate response; n= 310, 314)	137	155		
Week 14 (no response; n= 310, 314)	76	77		
Week 22 (good response; n= 301, 307)	103	96		
Week 22 (moderate response; n= 301, 307)	125	156		
Week 22 (no response; n= 301, 307)	73	55		
Week 30 (good response; n= 292, 297)	101	94		
Week 30 (moderate response; n= 292, 297)	133	155		
Week 30 (no response; n= 292, 297)	58	48		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With European League Against Rheumatism (EULAR) Response: Period 2

End point title	Number of Subjects With European League Against Rheumatism (EULAR) Response: Period 2

End point description:

EULAR response was based on DAS28 EULAR response criteria defined as Good response = DAS28 change >1.2 with DAS28 =<3.2; Moderate response = DAS28 change >0.6-=<1.2 with DAS28 >3.2-5.1; no-response = DAS28 change =<0.6 with DAS28 >5.1. The ITT Population was defined as all subjects who were randomized to study treatment. Here, "n" signifies number of subjects who were evaluable for the specified categories, for each arm respectively.

End point type	Secondary

End point timeframe:

Week 38, 46 and 54 (pre-dose)

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	280	143	143	
Units: subjects				
Week 38 (good response; n= 276, 141, 140)	110	51	49	
Week 38 (moderate response; n= 276, 141, 140)	132	62	66	
Week 38 (no response; n= 276, 141, 140)	34	28	25	
Week 46 (good response; n= 266, 138, 133)	107	46	49	
Week 46 (moderate response; n= 266, 138, 133)	126	64	67	
Week 46 (no response; n= 266, 138, 133)	33	28	17	
Week 54 (good response; n= 256, 129, 128)	118	53	50	
Week 54 (moderate response; n= 256, 129, 128)	109	56	62	
Week 54 (no response; n= 256, 129, 128)	29	20	16	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With European League Against Rheumatism (EULAR) Response: Period 3

End point title	Number of Subjects With European League Against Rheumatism (EULAR) Response: Period 3

End point description:

EULAR response was based on DAS28 EULAR response criteria defined as Good response = DAS28 change >1.2 with DAS28 =<3.2; Moderate response = DAS28 change >0.6-=<1.2 with DAS28 >3.2-5.1; no-response = DAS28 change =<0.6 with DAS28 >5.1. The ITT population included all subjects enrolled and treated with at least 1 dose of study treatment in Period 3. Here, "n" signifies number of subjects who were evaluable for the specified categories, for each arm respectively.

End point type	Secondary

End point timeframe:

Week 62, 70 and 78

End point values	Period 3: PF-06438179/PF-06438179/PF-06438179	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	253	126	126	
Units: subjects				
Week 62 (good response; n= 249, 123, 124)	122	50	57	
Week 62 (moderate response; n= 249, 123, 124)	102	56	54	
Week 62 (no response; n= 249, 123, 124)	25	17	13	
Week 70 (good response; n= 244, 119, 121)	127	56	52	
Week 70 (moderate response; n= 244, 119, 121)	92	48	54	
Week 70 (no response; n= 244, 119, 121)	25	15	15	
Week 78 (good response; n= 239, 114, 118)	133	58	57	
Week 78 (moderate response; n= 239, 114, 118)	84	45	53	
Week 78 (no response; n= 239, 114, 118)	22	11	8	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and Treatment Related TEAEs: Period 1

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and Treatment Related TEAEs: Period 1

End point description:

An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between first dose of study drug and up to Week 30 that were absent before treatment or that worsened relative to pre-treatment state. Treatment-related TEAE was any untoward medical occurrence attributed to study drug in a participant who received study drug. AEs included both serious and non-serious adverse events. Safety population was defined as all subjects who were randomized and received at least 1 dose of study treatment, analyzed by actual treatment received.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to Week 30

End point values	Period 1: Infliximab-EU Remicade (INX)	Period 1: PF-06438179		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	326	323		
Units: subjects				
TEAEs	176	185		
SAEs	20	16		
Treatment related TEAEs	75	81		
Treatment related SAEs	4	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and Treatment Related TEAEs: Period 2

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and Treatment Related TEAEs: Period 2

End point description:

An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between first dose of study drug and up to Week 30 that were absent before treatment or that worsened relative to pre-treatment state. Treatment-related TEAE was any untoward medical occurrence attributed to study drug in a participant who received study drug. AEs included both serious and non-serious adverse events. Safety population was defined as all subjects who were randomized and received at least 1 dose of study treatment, analyzed by actual treatment received.

End point type	Secondary

End point timeframe:

Baseline (Week 30 pre-dose) up to Week 54

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	280	143	143	
Units: subjects				
TEAEs	103	48	54	
SAEs	13	11	4	
Treatment related TEAEs	32	20	16	
Treatment related SAEs	2	5	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and Treatment Related TEAEs: Period 3

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs) and Treatment Related TEAEs: Period 3

End point description:

An AE was any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between first dose of study drug and up to Week 30 that were absent before treatment or that worsened relative to pre-treatment state. Treatment-related TEAE was any untoward medical occurrence attributed to study drug in a participant who received study drug. AEs included both serious and non-serious adverse events. Safety population was defined as all subjects who were randomized and received at least 1 dose of study treatment, analyzed by actual treatment received.

End point type	Secondary

End point timeframe:

Baseline (Week 54) up to Week 78

End point values	Period 3: PF-06438179/PF-06438179/PF-06438179	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	253	126	126	
Units: subjets				
TEAEs	73	38	37	
SAEs	3	3	6	
Treatment related TEAEs	22	10	8	
Treatment related SAEs	0	1	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs) of Grade 3 or Higher Severity: Period 1

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs) of Grade 3 or Higher Severity: Period 1

End point description:

AEs were graded in accordance with National Cancer Institute (NCI) Common Terminology Criteria for AEs (CTCAE) Version 4.03 as Grades 1= mild, Grade 2= moderate, Grade 3= severe, Grade 4= life threatening AEs and Grade 5= death related to AE. AEs of Grade 3 and higher severity are reported in this outcome measure. Safety population was defined as all subjects who were randomized and received at least 1 dose of study treatment, analyzed by actual treatment received.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to Week 30

End point values	Period 1: Infliximab-EU Remicade (INX)	Period 1: PF-06438179		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	326	323		
Units: subjects				
TEAEs (Grade 3)	34	34		
TEAEs (Grade 4)	6	1		
TEAEs (Grade 5)	1	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs) of Grade 3 or Higher Severity: Period 2

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs) of Grade 3 or Higher Severity: Period 2

End point description:

AEs were graded in accordance with National Cancer Institute (NCI) Common Terminology Criteria for AEs (CTCAE) Version 4.03 as Grades 1= mild, Grade 2= moderate, Grade 3= severe, Grade 4= life threatening AEs and Grade 5= death related to AE. AEs of Grade 3 and higher severity are reported in this outcome measure. Safety population was defined as all subjects who were randomized and received at least 1 dose of study treatment, analyzed by actual treatment received.

End point type	Secondary

End point timeframe:

Baseline (Week 30 pre-dose) up to Week 54

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	280	143	143	
Units: subjects				
TEAEs (Grade 3)	17	10	6	
TEAEs (Grade 4)	3	3	0	
TEAEs (Grade 5)	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects With Treatment Emergent Adverse Events (TEAEs) of Grade 3 or Higher Severity: Period 3

End point title	Number of subjects With Treatment Emergent Adverse Events (TEAEs) of Grade 3 or Higher Severity: Period 3

End point description:

AEs were graded in accordance with National Cancer Institute (NCI) Common Terminology Criteria for AEs (CTCAE) Version 4.03 as Grades 1= mild, Grade 2= moderate, Grade 3= severe, Grade 4= life threatening AEs and Grade 5= death related to AE. AEs of Grade 3 and higher severity are reported in this outcome measure. Safety population was defined as all subjects who were randomized and received at least 1 dose of study treatment, analyzed by actual treatment received.

End point type	Secondary

End point timeframe:

Baseline (Week 54 pre-dose) up to Week 78

End point values	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	126	126	253	
Units: subjects				
TEAEs (Grade 3)	3	7	4	
TEAEs (Grade 4)	0	0	1	
TEAEs (Grade 5)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Abnormalities: Treatment Period 1

End point title	Number of Subjects With Laboratory Abnormalities: Treatment Period 1

End point description:

Criteria for abnormality:hematology: hemoglobin, hematocrit, red blood cell count, lymphocytes, neutrophils: <0.8*lower limit of normal (LLN); platelets: >1.75*upper limit of normal (ULN); white blood cell count: <0.6*LLN; basophils, eosinophils, monocytes: >1.2*ULN. liver function: bilirubin: >1.5*ULN; aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase: >3.0*ULN; protein, albumin: <0.8*LLN></0>1.2*ULN; renal function:blood urea nitrogen,creatinine: >1.3*ULN; uric acid: >1.2*ULN; electrolytes: sodium, potassium, chloride, calcium, bicarbonate: <0.9*LLN,>1.1*ULN; urinalysis: pH<4.5, >8; glucose, protein, blood, ketones, urobilinogen, bilirubin, nitrite; Other(glucose: <0.6*LLN,>1.5*ULN). Safety population was defined as all subjects who are randomized and receive at least 1 dose of study treatment, analyzed by actual treatment received. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to Week 30

End point values	Period 1: Infliximab-EU Remicade (INX)	Period 1: PF-06438179		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	325	321		
Units: subjects	237	245		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Abnormalities: Treatment Period 2

End point title	Number of Subjects With Laboratory Abnormalities: Treatment Period 2

End point description:

Criteria for abnormality:hematology: hemoglobin, hematocrit, red blood cell count, lymphocytes, neutrophils: <0.8*lower limit of normal (LLN); platelets: >1.75*upper limit of normal (ULN); white blood cell count: <0.6*LLN; basophils, eosinophils, monocytes: >1.2*ULN. liver function: bilirubin: >1.5*ULN; aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase: >3.0*ULN; protein, albumin: <0.8*LLN></0>1.2*ULN; renal function:blood urea nitrogen,creatinine: >1.3*ULN; uric acid: >1.2*ULN; electrolytes: sodium, potassium, chloride, calcium, bicarbonate: <0.9*LLN,>1.1*ULN; urinalysis: pH<4.5, >8; glucose, protein, blood, ketones, urobilinogen, bilirubin, nitrite; Other(glucose: <0.6*LLN,>1.5*ULN). Safety population was defined as all subjects who are randomized and receive at least 1 dose of study treatment, analyzed by actual treatment received. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline (Week 30 pre-dose) up to Week 54

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	279	142	141	
Units: subjects	154	83	63	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Abnormalities: Treatment Period 3

End point title	Number of Subjects With Laboratory Abnormalities: Treatment Period 3

End point description:

Criteria for abnormality:hematology: hemoglobin, hematocrit, red blood cell count, lymphocytes, neutrophils: <0.8*lower limit of normal (LLN); platelets: >1.75*upper limit of normal (ULN); white blood cell count: <0.6*LLN; basophils, eosinophils, monocytes: >1.2*ULN. liver function: bilirubin: >1.5*ULN; aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase: >3.0*ULN;

protein, albumin: <0.8*LLN></0>1.2*ULN; renal function:blood urea nitrogen,creatinine: >1.3*ULN; uric acid: >1.2*ULN; electrolytes: sodium, potassium, chloride, calcium, bicarbonate: <0.9*LLN,>1.1*ULN; urinalysis: pH<4.5, >8; glucose, protein, blood, ketones, urobilinogen, bilirubin, nitrite; Other(glucose: <0.6*LLN,>1.5*ULN). Safety population was defined as all subjects who are randomized and receive at least 1 dose of study treatment, analyzed by actual treatment received. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline (Week 54 pre-dose) up to Week 78

End point values	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	123	126	250	
Units: subjects	72	61	127	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Tender Joint Count and Swollen Joint Count at Week 2, 4, 6, 12, 14, 22 and 30: Period 1

End point title	Change From Baseline in Tender Joint Count and Swollen Joint Count at Week 2, 4, 6, 12, 14, 22 and 30: Period 1

End point description:

Tender joint count was an assessment of 68 joints (upper body, upper extremity, and lower extremity). Each joint's response to pressure/motion was assessed as: Present or Absent. Swollen joint count was an assessment of 66 joints (upper body, upper extremity, and lower extremity). Each joint was assessed for swelling as: Present or Absent. The ITT Population was defined as all subjects who were randomized to study treatment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 2, 4, 6, 12, 14, 22 and 30

End point values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	321	325		
Units: joints				
arithmetic mean (standard deviation)				
Tender joint count:Baseline; n= 321,325	24.7 (± 13.90)	25.8 (± 12.89)		
Tender joint count:Change at Week 2; n= 319,324	-5.9 (± 8.78)	-7.5 (± 8.39)		

Tender joint count:Change at Week 4; n= 317,321	-9.5 (± 10.02)	-10.4 (± 9.41)		
Tender joint count:Change at Week 6; n= 313,319	-10.6 (± 11.17)	-12.1 (± 10.12)		
Tender joint count:Change at Week 12; n= 311,318	-12.1 (± 11.84)	-13.2 (± 11.51)		
Tender joint count:Change at Week 14; n= 311,316	-11.8 (± 12.50)	-13.0 (± 12.15)		
Tender joint count:Change at Week 22; n= 301,311	-13.2 (± 12.62)	-15.2 (± 12.93)		
Tender joint count:Change at Week 30; n= 294,298	-14.4 (± 13.19)	-15.6 (± 12.57)		
Swollen joint count:Baseline; n= 321,325	16.1 (± 9.44)	16.3 (± 8.70)		
Swollen joint count:Change at Week 2; n= 319,324	-5.5 (± 6.89)	-5.7 (± 7.27)		
Swollen joint count:Change at Week 4; n= 317,321	-7.8 (± 7.75)	-7.9 (± 7.39)		
Swollen joint count:Change at Week 6; n= 313,319	-8.6 (± 7.99)	-9.0 (± 7.92)		
Swollen joint count:Change at Week 12; n= 311,318	-9.6 (± 8.61)	-9.6 (± 8.39)		
Swollen joint count:Change at Week 14; n= 311,316	-9.3 (± 8.87)	-9.6 (± 8.44)		
Swollen joint count:Change at Week 22; n= 301,311	-10.5 (± 8.77)	-10.2 (± 7.94)		
Swollen joint count:Change at Week 30; n= 294,298	-11.0 (± 9.33)	-10.7 (± 8.52)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Tender Joint Count and Swollen Joint Count at Week 38, 46 and 54: Period 2

End point title	Change From Baseline in Tender Joint Count and Swollen Joint Count at Week 38, 46 and 54: Period 2

End point description:

Tender joint count was an assessment of 68 joints (upper body, upper extremity, and lower extremity). Each joint's response to pressure/motion was assessed as: Present or Absent. Swollen joint count was an assessment of 66 joints (upper body, upper extremity, and lower extremity). Each joint was assessed for swelling as: Present or Absent. The ITT Population was defined as all subjects who were randomized to study treatment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 30 pre-dose), Week 38, 46 and 54

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	278	142	141	
Units: joints				
arithmetic mean (standard deviation)				
Tender joint count:Baseline;n= 278,142,141	10.2 (± 11.74)	10.2 (± 11.96)	9.1 (± 8.89)	
Tender joint count:Change at Week 38;n=277,141,141	-1.3 (± 6.74)	-0.5 (± 8.86)	-1.0 (± 6.03)	
Tender joint count:Change at Week 46;n=269,138,133	-1.6 (± 7.87)	-1.0 (± 9.32)	-0.8 (± 7.77)	
Tender joint count:Change at Week 54;n=260,130,129	-1.7 (± 7.96)	-1.7 (± 10.23)	-0.5 (± 9.03)	
Swollen joint count:Baseline;n=278,142,141	4.9 (± 6.46)	5.3 (± 6.57)	4.6 (± 5.35)	
Swollen jointcount:Change at Week 38;n=277,141,141	-0.8 (± 4.19)	-0.1 (± 4.90)	-0.3 (± 3.93)	
Swollen jointcount:Change at Week 46;n=269,138,133	-1.2 (± 5.20)	0.0 (± 5.54)	-0.5 (± 4.22)	
Swollen jointcount:Change at Week 54;n=260,130,129	-1.3 (± 5.52)	-0.9 (± 7.02)	-0.7 (± 4.10)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Tender Joint Count and Swollen Joint Count at Week 62, 70 and 78: Period 3

End point title	Change From Baseline in Tender Joint Count and Swollen Joint Count at Week 62, 70 and 78: Period 3

End point description:

Tender joint count was an assessment of 68 joints (upper body, upper extremity, and lower extremity). Each joint's response to pressure/motion was assessed as: Present or Absent. Swollen joint count was an assessment of 66 joints (upper body, upper extremity, and lower extremity). Each joint was assessed for swelling as: Present or Absent. The ITT population included all subjects enrolled and treated with at least 1 dose of study treatment in Period 3. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 54 pre-dose), Week 62, 70 and 78

End point values	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	123	126	249	
Units: joints				
arithmetic mean (standard deviation)				
Tender joint count:Baseline;n=249,123,126	7.5 (± 9.21)	7.4 (± 7.99)	7.5 (± 9.51)	

Tender joint count:Change at Week 62;n=249,123,124	0.3 (± 5.21)	-0.8 (± 5.18)	-0.7 (± 5.88)	
Tender joint count:Change at Week 70;n=244,119,122	-0.6 (± 5.14)	-1.0 (± 5.51)	-1.4 (± 6.32)	
Tender joint count:Change at Week 78;n=239,116,118	-1.0 (± 5.82)	-1.4 (± 6.63)	-1.7 (± 6.57)	
Swollen jointcount:Baseline; n=249,123,126	4.1 (± 5.16)	3.5 (± 4.28)	3.4 (± 5.72)	
Swollen jointcount:Change at Week 62;n=249,123,124	0.0 (± 4.41)	-0.3 (± 2.72)	-0.3 (± 3.76)	
Swollen jointcount:Change at Week 70;n=244,119,122	-0.4 (± 4.12)	-0.5 (± 2.48)	-0.7 (± 4.60)	
Swollen jointcount:Change at Week 78;n=239,116,118	-0.5 (± 4.00)	-0.2 (± 3.14)	-0.9 (± 4.63)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient's Assessment of Arthritis Pain (PAAP), Patient's Global Assessment of Arthritis (PGA) and Physician's Global Assessment of Arthritis (PGAA) at Week 2, 4, 6, 12, 14, 22, 30: Period 1

End point title	Change From Baseline in Patient's Assessment of Arthritis Pain (PAAP), Patient's Global Assessment of Arthritis (PGA) and Physician's Global Assessment of Arthritis (PGAA) at Week 2, 4, 6, 12, 14, 22, 30: Period 1

End point description:

PAAP: Subjects assessed the severity of their arthritis pain by using 100 mm VAS ranging from 0-100(no pain-most severe pain):corresponded to the magnitude of their pain, higher scores=more pain. PGA: subjects were asked the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" and response was recorded on 100 mm VAS ranging from 0-100(no pain-most severe pain), where higher scores=worse health condition. PGAA: Subjects were assessed how their overall arthritis appears at the time of the visit. The evaluation was based on the subject's disease signs, functional capacity and physical examination, and was independent of the PAAP and PGA assessments. The physician's response was recorded using a 100 mm VAS ranging from 0-100(no pain-most severe pain), where higher scores=more disease activity. ITT Population. Here, "Number of Subjects Analyzed"=subjects evaluable for this outcome measure and "n"=subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 2, 4, 6, 12, 14, 22 and 30

End point values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	321	325		
Units: units on a scale				
arithmetic mean (standard deviation)				
PAAP: Baseline; n= 321, 325	63.514 (± 20.5903)	63.098 (± 21.5442)		
PAAP: Change at Week 2; n= 320, 324	-15.724 (± 21.9589)	-15.360 (± 19.4328)		

PAAP: Change at Week 4; n= 317, 321	-21.609 (± 22.3825)	-20.552 (± 21.2670)		
PAAP: Change at Week 6; n= 314, 320	-23.917 (± 25.0213)	-22.797 (± 22.9133)		
PAAP: Change at Week 12; n= 311, 318	-25.364 (± 25.6602)	-25.829 (± 24.8304)		
PAAP: Change at Week 14; n= 311, 316	-26.131 (± 26.8712)	-25.077 (± 25.0536)		
PAAP: Change at week 22; n= 301, 311	-27.844 (± 27.0039)	-25.788 (± 25.3225)		
PAAP: Change at Week 30; n= 294, 298	-29.150 (± 27.9802)	-28.853 (± 26.7252)		
PGA: Baseline; n= 321, 325	65.340 (± 20.7209)	63.752 (± 22.9105)		
PGA: Change at Week 2; n= 320, 324	-17.262 (± 22.8767)	-16.504 (± 20.3188)		
PGA: Change at Week 4; n= 317, 321	-23.393 (± 23.3769)	-21.355 (± 23.6005)		
PGA: Change at Week 6; n= 314, 320	-25.536 (± 24.8041)	-23.314 (± 24.2005)		
PGA: Change at Week 12; n= 311, 317	-26.882 (± 25.3270)	-26.535 (± 26.3998)		
PGA: Change at Week 14; n= 311, 316	-27.583 (± 26.7955)	-25.323 (± 26.8562)		
PGA: Change at week 22; n= 301, 310	-28.558 (± 27.5077)	-26.486 (± 26.7141)		
PGA: Change at Week 30; n= 294, 298	-29.186 (± 28.6488)	-28.814 (± 28.5929)		
PGAA: Baseline; n= 319, 325	65.362 (± 16.2520)	64.126 (± 16.7220)		
PGAA: Change at Week 2; n= 318, 324	-21.913 (± 18.5574)	-20.143 (± 17.1407)		
PGAA: Change at Week 4; n= 315, 321	-29.724 (± 19.2226)	-27.905 (± 17.9803)		
PGAA: Change at Week 6; n= 312, 320	-33.319 (± 20.1143)	-30.958 (± 18.9303)		
PGAA: Change at Week 12; n= 310, 318	-34.827 (± 19.8162)	-33.919 (± 19.7020)		
PGAA: Change at Week 14; n= 310, 316	-35.870 (± 21.4707)	-34.175 (± 20.6526)		
PGAA: Change at Week 22; n= 300, 311	-37.542 (± 20.8619)	-36.118 (± 20.6564)		
PGAA: Change at Week 30; n= 293, 298	-39.842 (± 22.0276)	-36.666 (± 22.1598)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient's Assessment of Arthritis Pain (PAAP), Patient's Global Assessment of Arthritis (PGA) and Physician's Global Assessment of Arthritis (PGAA) at Week 38, 46 and 54: Period 2

End point title	Change From Baseline in Patient's Assessment of Arthritis Pain (PAAP), Patient's Global Assessment of Arthritis (PGA) and Physician's Global Assessment of Arthritis (PGAA) at Week 38, 46 and 54: Period 2

End point description:

PAAP: Subjects assessed the severity of their arthritis pain by using 100 mm VAS ranging from 0-100

(no pain-most severe pain):corresponded to the magnitude of their pain, higher scores=more pain. PGA: subjects were asked the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" and response was recorded on 100 mm VAS ranging from 0-100(no pain-most severe pain), where higher scores=worse health condition. PGAA: Subjects were assessed how their overall arthritis appears at the time of the visit. The evaluation was based on the subject's disease signs, functional capacity and physical examination, and was independent of the PAAP and PGA assessments. The physician's response was recorded using a 100 mm VAS ranging from 0-100(no pain-most severe pain), where higher scores=more disease activity. ITT Population. Here, "Number of Subjects Analyzed"=subjects evaluable for this outcome measure and "n"=subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 30 pre-dose), Week 38, 46 and 54

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	278	142	141	
Units: units on a scale				
arithmetic mean (standard deviation)				
PAAP: Baseline; n= 278, 142, 141	33.137 (± 24.2922)	33.331 (± 22.2738)	32.559 (± 22.2702)	
PAAP: Change at Week 38; n= 277, 141, 141	-0.014 (± 18.7502)	1.440 (± 14.9902)	-0.705 (± 18.9147)	
PAAP: Change at Week 46; n= 269, 138, 133	-2.230 (± 20.0201)	1.087 (± 21.5811)	2.188 (± 20.7319)	
PAAP: Change at Week 54; n= 259, 130, 129	-1.416 (± 20.7823)	-0.492 (± 20.8000)	1.365 (± 24.8362)	
PGA: Baseline; n= 278, 142, 141	35.104 (± 24.8444)	33.268 (± 22.2621)	34.029 (± 22.7172)	
PGA: Change at Week 38; n= 277, 141, 141	-1.628 (± 19.1471)	1.582 (± 16.0776)	-1.086 (± 17.5787)	
PGA: Change at Week 46; n= 269, 138, 133	-3.171 (± 20.3050)	0.558 (± 20.6610)	0.535 (± 21.3947)	
PGA: Change at Week 54; n= 259, 130, 129	-2.929 (± 20.9396)	-0.538 (± 21.1331)	0.776 (± 23.8743)	
PGAA: Baseline; n= 278, 142, 141	25.124 (± 19.0943)	27.294 (± 18.8148)	26.091 (± 17.9503)	
PGAA: Change at Week 38; n= 277, 141, 141	-1.254 (± 12.4789)	0.588 (± 16.5232)	-1.852 (± 15.4699)	
PGAA: Change at Week 46; n= 269, 138, 133	-2.470 (± 13.9135)	0.625 (± 20.0163)	-0.700 (± 18.8038)	
PGAA: Change at Week 54; n= 258, 130, 129	-2.252 (± 17.0422)	-3.398 (± 20.0381)	-2.969 (± 20.1498)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient's Assessment of Arthritis Pain (PAAP), Patient's Global Assessment of Arthritis (PGA) and Physician's Global Assessment of Arthritis (PGAA) at Week 62, 70 and 78: Period 3

End point title	Change From Baseline in Patient's Assessment of Arthritis Pain

	(PAAP), Patient's Global Assessment of Arthritis (PGA) and Physician's Global Assessment of Arthritis (PGAA) at Week 62, 70 and 78: Period 3

End point description:

PAAP: Subjects assessed the severity of their arthritis pain by using 100 mm VAS ranging from 0-100(no pain-most severe pain):corresponded to the magnitude of their pain, higher scores=more pain. PGA: subjects were asked the following question, "Considering all the ways your arthritis affects you, how are you feeling today?" and response was recorded on 100 mm VAS ranging from 0-100(no pain-most severe pain), where higher scores=worse health condition. PGAA: Subjects were assessed how their overall arthritis appears at the time of the visit. The evaluation was based on the subject's disease signs, functional capacity and physical examination, and was independent of the PAAP and PGA assessments. The physician's response was recorded using a 100 mm VAS ranging from 0-100(no pain-most severe pain), where higher scores=more disease activity. ITT Population. Here, "Number of Subjects Analyzed"=subjects evaluable for this outcome measure and "n"=subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 54 pre-dose), Week 62, 70 and 78

End point values	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	123	126	249	
Units: units on a scale				
arithmetic mean (standard deviation)				
PAAP: Baseline; n= 249, 123, 126	31.659 (± 23.2900)	31.225 (± 22.9366)	30.395 (± 23.7412)	
PAAP: Change at Week 62; n= 249, 123, 124	0.276 (± 12.2744)	-1.790 (± 16.6740)	-0.025 (± 15.8259)	
PAAP: Change at Week 70; n= 244, 118, 122	-0.297 (± 15.4108)	-0.970 (± 16.7170)	-2.948 (± 18.1105)	
PAAP: Change at Week 78; n= 238, 116, 118	-2.900 (± 18.0663)	-3.918 (± 20.9632)	-3.552 (± 18.8760)	
PGA: Baseline; n= 249, 123, 126	31.130 (± 23.3603)	32.710 (± 22.6365)	30.841 (± 23.7807)	
PGA: Change at Week 62; n= 249, 123, 124	1.463 (± 13.6899)	-2.226 (± 15.3415)	0.240 (± 16.2724)	
PGA: Change at Week 70; n= 244, 119, 122	0.101 (± 14.4260)	-2.093 (± 16.2677)	-1.764 (± 18.7038)	
PGA: Change at Week 78; n= 239, 115, 118	-2.339 (± 17.0453)	-3.758 (± 19.5447)	-2.880 (± 19.6643)	
PGAA: Baseline; n= 249, 123, 126	21.780 (± 17.3354)	20.705 (± 16.9587)	21.305 (± 17.6278)	
PGAA: Change at Week 62; n= 249, 123, 124	2.659 (± 14.6314)	-0.499 (± 12.9483)	-0.381 (± 13.6810)	
PGAA: Change at Week 70; n= 244, 119, 122	-1.160 (± 12.7665)	-0.810 (± 15.0274)	-3.217 (± 14.1581)	
PGAA: Change at Week 78; n= 239, 116, 118	0.681 (± 15.0989)	-0.159 (± 17.2024)	-2.217 (± 15.3894)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in High Sensitivity C-Reactive Protein (hs-CRP) Concentration at Week 2, 4, 6, 12, 14, 22 and 30: Period 1

End point title	Change From Baseline in High Sensitivity C-Reactive Protein (hs-CRP) Concentration at Week 2, 4, 6, 12, 14, 22 and 30: Period 1

End point description:

The ITT Population was defined as all subjects who were randomized to study treatment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and “n” signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 2, 4, 6, 12, 14, 22 and 30

End point values	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	321	325		
Units: milligram/litres				
arithmetic mean (standard deviation)				
Baseline; n= 321, 325	25.916 (± 24.3118)	25.366 (± 28.4866)		
Change at Week 2; n= 318, 324	-17.183 (± 20.8107)	-16.140 (± 24.2442)		
Change at Week 4; n= 312, 315	-15.555 (± 19.5227)	-13.407 (± 33.9136)		
Change at Week 6; n= 313, 320	-14.078 (± 20.4984)	-13.247 (± 27.7801)		
Change at Week 12; n= 311, 317	-12.502 (± 23.9435)	-12.525 (± 27.8736)		
Change at Week 14; n= 310, 314	-12.613 (± 23.2548)	-12.392 (± 29.3267)		
Change at Week 22; n= 301, 308	-11.195 (± 24.5225)	-11.422 (± 31.0610)		
Change at Week 30; n= 292, 297	-12.165 (± 25.6612)	-12.390 (± 30.0352)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in High Sensitivity C-Reactive Protein (hs-CRP) Concentration at Week 38, 46 and 54: Period 2

End point title	Change From Baseline in High Sensitivity C-Reactive Protein (hs-CRP) Concentration at Week 38, 46 and 54: Period 2

End point description:

The ITT Population was defined as all subjects who were randomized to study treatment. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and “n” signifies subjects who were evaluable at specified time points.

End point type	Secondary
End point timeframe: Baseline (Week 30 pre-dose), Week 38, 46 and 54	

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	278	142	141	
Units: milligrams/litres				
arithmetic mean (standard deviation)				
Baseline; n= 278, 142, 141	12.970 (± 19.1927)	14.427 (± 21.1595)	10.847 (± 14.8018)	
Change at Week 38; n= 276, 141, 140	0.496 (± 18.7859)	1.805 (± 19.5138)	0.093 (± 14.8441)	
Change at Week 46; n= 266, 138, 133	1.210 (± 16.1727)	3.996 (± 24.4986)	0.798 (± 15.7687)	
Change at Week 54; n= 256, 129, 128	0.639 (± 21.1226)	2.988 (± 24.5492)	1.264 (± 13.6788)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in High Sensitivity C-Reactive Protein (hs-CRP) Concentration at Week 62, 70 and 78: Period 3

End point title	Change From Baseline in High Sensitivity C-Reactive Protein (hs-CRP) Concentration at Week 62, 70 and 78: Period 3
End point description: The ITT population included all subjects enrolled and treated with at least 1 dose of study treatment in Period 3. Here, "Number of Subjects Analyzed" signifies subjects who were evaluable for this endpoint and “n” signifies subjects who were evaluable at specified time points.	
End point type	Secondary
End point timeframe: Baseline (Week 54 pre-dose), Week 62, 70 and 78	

End point values	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	126	126	253	
Units: milligrams/litres				
arithmetic mean (standard deviation)				
Baseline; n= 249, 123, 126	16.096 (± 24.1595)	11.985 (± 13.8159)	13.112 (± 21.3781)	
Change at Week 62; n= 249, 123, 124	-3.648 (± 21.6177)	-0.541 (± 9.3198)	-0.635 (± 19.9660)	

Change at Week 70; n= 244, 119, 121	-4.199 (± 22.3368)	-0.339 (± 11.7095)	-0.320 (± 23.1234)	
Change at Week 78; n= 239, 115, 118	-3.565 (± 23.9800)	0.811 (± 14.7061)	-1.660 (± 19.6340)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Positive Anti-drug Antibodies (ADA) and Neutralizing Antibodies (Nab) Status: Period 1

End point title	Number of Subjects With Positive Anti-drug Antibodies (ADA) and Neutralizing Antibodies (Nab) Status: Period 1

End point description:

ADA positive results was defined as ADA titer level >=1.30 and NAb positive was defined as NAb titer level >=0.70. Safety population was defined as all subjects who were randomized and received at least 1 dose of study treatment, analyzed by actual treatment received. Here "n" signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to Week 30

End point values	Period 1: Infliximab-EU Remicade (INX)	Period 1: PF-06438179		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	326	323		
Units: subjects				
ADA; n= 323, 326	167	157		
NAb; n= 157, 167	143	124		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Positive Anti-drug Antibodies (ADA) and Neutralizing Antibodies (Nab) Status: Period 2

End point title	Number of Subjects With Positive Anti-drug Antibodies (ADA) and Neutralizing Antibodies (Nab) Status: Period 2

End point description:

ADA positive results was defined as ADA titer level >=1.30 and NAb positive was defined as NAb titer level >=0.70. Safety population was defined as all subjects who were randomized and received at least 1 dose of study treatment, analyzed by actual treatment received. Here "n" signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 30 pre-dose) up to Week 54

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	280	143	143	
Units: subjects				
ADA; n= 323, 326	146	86	83	
NAb; n= 146, 86, 83	118	73	65	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Positive Anti-drug Antibodies (ADA) and Neutralizing Antibodies (Nab) Status: Period 3

End point title	Number of Subjects With Positive Anti-drug Antibodies (ADA) and Neutralizing Antibodies (Nab) Status: Period 3

End point description:

ADA positive results was defined as ADA titer level >=1.30 and NAb positive was defined as NAb titer level >=0.70. Safety population was defined as all subjects who were randomized and received at least 1 dose of study treatment, analyzed by actual treatment received. Here "n" signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 54 pre-dose) up to Week 78

End point values	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	126	126	253	
Units: subjects				
ADA; n= 323, 326	66	72	119	
NAb; n= 119, 66, 72	58	60	105	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration Versus Time Summary: Period 1

End point title	Serum Concentration Versus Time Summary: Period 1

End point description:

Pharmacokinetic population: all treated subjects from per protocol (PP) population, who had at least 1 post-dose drug concentration measurement during Period 1. PP population: all subjects who were randomized and received the study treatment as planned up to Week 14, with no major protocol deviations. Here "n" signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Pre dose on Day 1, 15, 43, 99, 155 and 211; 2 hours post dose on Day 1 and 99; and 336 hours post dose on Day 29

End point values	Period 1: Infliximab-EU Remicade (INX)	Period 1: PF-06438179		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	326	323		
Units: nanograms/milliliters				
median (standard deviation)				
Day 1: 0 hours; n= 322, 323	656.2 (± 6583.8)	1635 (± 11163)		
Day 1: 2 hours; n= 319, 322	62220 (± 22129)	65310 (± 24920)		
Day 15: 0 hours; n= 316, 323	16690 (± 8002.7)	17350 (± 8391.4)		
Day 29: 336 hours; n= 308, 314	21570 (± 10986)	23640 (± 12357)		
Day 43: 0 hours; n= 308, 315	10100 (± 7721.7)	11440 (± 10101)		
Day 99: 0 hours; n= 302, 310	2559 (± 6360.3)	3547 (± 9559.2)		
Day 99: 2 hours; n= 297, 299	73350 (± 41410)	76030 (± 39407)		
Day 155: 0 hours; n= 295, 303	1566 (± 2321.4)	2051 (± 3440.9)		
Day 211: 0 hours; n= 281, 290	2112 (± 11703)	1781 (± 2765.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration Versus Time Summary: Period 2

End point title	Serum Concentration Versus Time Summary: Period 2

End point description:

Pharmacokinetic population: all treated subjects from per protocol (PP) population, who had at least 1 post-dose drug concentration measurement during Period 1. PP population: all subjects who were randomized and received the study treatment as planned up to Week 14, with no major protocol deviations. Here "n" signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Pre dose on Day 211, 267, 379 and 547

End point values	Period 2: PF-06438179/PF-06438179	Period 2: INX/INX	Period 2: INX/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	280	143	143	
Units: nanograms/milliliters				
arithmetic mean (standard deviation)				
Day 211: 0 hours; n= 278, 143, 142	1801 (± 2773.4)	1083 (± 1763.6)	1819 (± 2393.5)	
Day 267: 0 hours; n= 272, 136, 133	1855 (± 2871.7)	1208 (± 1926.5)	1620 (± 2413.7)	
Day 379: 0 hours; n= 248, 125, 125	2075 (± 4054.6)	1823 (± 6110.8)	1734 (± 2725.2)	
Day 547: 0 hours; n= 16, 14, 11	499.6 (± 1373.0)	212.7 (± 405.18)	3305 (± 8429.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration Versus Time Summary: Period 3

End point title	Serum Concentration Versus Time Summary: Period 3

End point description:

Pharmacokinetic population: all treated subjects from per protocol (PP) population, who had at least 1 post-dose drug concentration measurement during Period 1. PP population: all subjects who were randomized and received the study treatment as planned up to Week 14, with no major protocol deviations. Here "n" signifies subjects who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Pre dose on Day 379, 435 and 547

End point values	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	126	126	253	
Units: nanograms/milliliters				
arithmetic mean (standard deviation)				
Day 379: 0 hours; n= 250, 125, 125	1823 (± 6110.8)	1734 (± 2725.2)	2078 (± 4044.0)	
Day 435: 0 hours; n= 243, 118, 123	1388 (± 2387.4)	1572 (± 2543.4)	1913 (± 2838.0)	
Day 547: 0 hours; n= 243, 121, 119	1663 (± 5305.7)	1482 (± 2441.6)	1707 (± 2512.9)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Period 1: Baseline (Day 1) up to Week 30, Period 2: Baseline (Week 30 pre-dose) up to Week 54, Period 3: Baseline (Week 54 pre-dose) up to Week 78

Adverse event reporting additional description:

Safety population: all subjects who are randomized and receive at least 1 dose of study drug, analyzed by actual treatment received. Same event may appear as both AE and SAE. However, what is presented are distinct events. An event may be serious in 1 and non-serious in other subject, or 1 subject may experience both serious and non-serious event.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0; 20.0

Reporting groups

Reporting group title	Period 1: PF-06438179

Reporting group description:

Subjects were scheduled to receive intravenous infusions of PF-06438179 at a dose of 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessment. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks.

Reporting group title	Period 1: Infliximab-EU Remicade (INX)

Reporting group description:

Subjects were scheduled to receive intravenous infusions of INX at a dose of 3 mg/kg on Weeks 0, 2, 6 followed by a maintenance dose every 8 weeks at Weeks 14 and 22 in Period 1 which ended with the completion of the Week 30 pre-dose assessment. For subjects who failed to achieve a minimum clinical response or lost clinical response (after Week 14 assessments), dose was increased to 5 mg/kg per infusion every 8 weeks.

Reporting group title	Period 2: PF-06438179/PF-06438179

Reporting group description:

Subjects randomized to receive intravenous infusions of PF-06438179 in Period 1 were scheduled to receive PF-06438179 in Period 2 at a dose of 3 mg/kg or 5 mg/kg on Weeks 30, 38 and 46. Period 2 ended with the completion of the Week 54 pre-dose assessments.

Reporting group title	Period 2: INX/INX

Reporting group description:

Subjects randomized to receive intravenous infusions of INX in Period 1 were scheduled to receive INX in Period 2 at a dose of 3 mg/kg or 5 mg/kg on Weeks 30, 38 and 46. Period 2 ended with the completion of the Week 54 pre-dose assessments.

Reporting group title	Period 2: INX/PF-06438179

Reporting group description:

Subjects randomized to receive intravenous infusions of INX in Period 1 were scheduled to receive PF-06438179 in Period 2 at a dose of 3 mg/kg or 5 mg/kg on Weeks 30, 38 and 46. Period 2 ended with the completion of the Week 54 pre-dose assessments.

Reporting group title	Period 3: PF-06438179/PF-06438179/PF-06438179

Reporting group description:

Subjects received intravenous infusions of PF-06438179 in Period 1 and Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Reporting group title	Period 3: INX/INX/PF-06438179

Reporting group description:

Subjects received intravenous infusions of INX in Period 1 and Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Reporting group title	Period 3: INX/PF-06438179/PF-06438179

Reporting group description:

Subjects received intravenous infusions of INX in Period 1 and PF-06438179 in Period 2. In Period 3 they were scheduled to receive PF-06438179 at a dose of 3 mg/kg or 5 mg/kg on Weeks 54, 62 and 70. Period 3 ended at Week 78.

Serious adverse events	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)	Period 2: PF-06438179/PF-06438179
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 323 (4.95%)	20 / 326 (6.13%)	13 / 280 (4.64%)
number of deaths (all causes)	1	1	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal squamous cell carcinoma			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular lymphoma			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Shock			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Venous stenosis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	2 / 323 (0.62%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ disorder			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Systemic inflammatory response syndrome			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Genital prolapse			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometriosis			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menometrorrhagia			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Cartilage injury			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			

alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Acute myocardial infarction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	2 / 323 (0.62%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Angina unstable			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	2 / 326 (0.61%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Transient ischaemic attack			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood disorder			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Keratitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diverticular perforation			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			

subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Rheumatoid arthritis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	2 / 323 (0.62%)	2 / 326 (0.61%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Purulent synovitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 323 (0.31%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 323 (0.00%)	1 / 326 (0.31%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			

subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	1 / 280 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone abscess			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 323 (0.00%)	0 / 326 (0.00%)	0 / 280 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Period 2: INX/INX	Period 2: INX/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-06438179
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 143 (7.69%)	4 / 143 (2.80%)	3 / 253 (1.19%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal squamous cell carcinoma			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular lymphoma			
subjects affected / exposed	0 / 143 (0.00%)	1 / 143 (0.70%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Shock			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous stenosis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ disorder			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Genital prolapse			
subjects affected / exposed	0 / 143 (0.00%)	1 / 143 (0.70%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometriosis			

subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menometrorrhagia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary mass			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Cartilage injury			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hip fracture alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 143 (0.00%)	1 / 143 (0.70%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Transient ischaemic attack			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood disorder			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Keratitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diverticular perforation			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			

Cholecystitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Rheumatoid arthritis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	2 / 143 (1.40%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 143 (0.70%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Purulent synovitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 143 (0.00%)	1 / 143 (0.70%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone abscess			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 143 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 126 (2.38%)	6 / 126 (4.76%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular lymphoma			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Shock			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous stenosis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ disorder			

alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Genital prolapse			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometriosis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menometrorrhagia			

subjects affected / exposed	0 / 126 (0.00%)	1 / 126 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Cartilage injury			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	1 / 126 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Femur fracture			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 126 (0.79%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Transient ischaemic attack			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood disorder			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			

Keratitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diverticular perforation			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal and connective tissue disorders			
Rheumatoid arthritis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 126 (0.00%)	1 / 126 (0.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	1 / 126 (0.79%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	1 / 126 (0.79%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis norovirus			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Purulent synovitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pyelonephritis acute			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	1 / 126 (0.79%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter infection			

subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone abscess			
subjects affected / exposed	1 / 126 (0.79%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	0 / 126 (0.00%)	1 / 126 (0.79%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	0 / 126 (0.00%)	1 / 126 (0.79%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Period 1: PF-06438179	Period 1: Infliximab-EU Remicade (INX)	Period 2: PF-06438179/PF-06438179
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 323 (11.76%)	35 / 326 (10.74%)	8 / 280 (2.86%)
Investigations			
Alanine aminotransferase increased			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	19 / 323 (5.88%)	15 / 326 (4.60%)	0 / 280 (0.00%)
occurrences (all)	20	21	0
Injury, poisoning and procedural complications			
Infusion related reaction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	19 / 323 (5.88%)	21 / 326 (6.44%)	8 / 280 (2.86%)
occurrences (all)	21	28	9

Non-serious adverse events	Period 2: INX/INX	Period 2: INX/PF-06438179	Period 3: PF-06438179/PF-06438179/PF-

			06438179
Total subjects affected by non-serious adverse events subjects affected / exposed	11 / 143 (7.69%)	6 / 143 (4.20%)	0 / 253 (0.00%)
Investigations Alanine aminotransferase increased alternative dictionary used: MedDRA 19.0 subjects affected / exposed occurrences (all)	0 / 143 (0.00%) 0	0 / 143 (0.00%) 0	0 / 253 (0.00%) 0
Injury, poisoning and procedural complications Infusion related reaction alternative dictionary used: MedDRA 19.0 subjects affected / exposed occurrences (all)	11 / 143 (7.69%) 15	6 / 143 (4.20%) 11	0 / 253 (0.00%) 0

Non-serious adverse events	Period 3: INX/INX/PF-06438179	Period 3: INX/PF-06438179/PF-06438179	
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 126 (0.00%)	0 / 126 (0.00%)	
Investigations Alanine aminotransferase increased alternative dictionary used: MedDRA 19.0 subjects affected / exposed occurrences (all)	0 / 126 (0.00%) 0	0 / 126 (0.00%) 0	
Injury, poisoning and procedural complications Infusion related reaction alternative dictionary used: MedDRA 19.0 subjects affected / exposed occurrences (all)	0 / 126 (0.00%) 0	0 / 126 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 September 2014	Protocol Amendment 1
04 February 2015	Protocol Amendment 2

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported