Clinical trial results:
A randomized phase 2 non-comparative study of the efficacy of PF-04691502 and PF-05212384 in patients with recurrent endometrial cancer

Summary

EudraCT number	2011-003062-32
Trial protocol	SK ES PL DE GB
Global end of trial date	25 December 2015

Results information

Result version number	v1 (current)
This version publication date	14 December 2016
First version publication date	14 December 2016

Trial information

Trial identification

Sponsor protocol code	B1271004

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 East 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	27 July 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 April 2014
Global end of trial reached?	Yes
Global end of trial date	25 December 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Arm A: To assess the clinical benefit response (CBR) of the oral PI3K/mTOR inhibitor PF-04691502 in patients with recurrent endometrial cancer that is classified as PI3K basal.

Arm B: To assess the CBR of the IV PI3K/mTOR inhibitor PF-05212384 in patients with recurrent endometrial cancer that is classified as PI3K basal.

Arm C: To assess the CBR of the oral PI3K/mTOR inhibitor PF-04691502 in patients with recurrent endometrial cancer that is classified as PI3K activated.

Arm D: To assess the CBR of the IV PI3K/mTOR inhibitor PF-05212384 in patients with recurrent endometrial cancer that is classified as PI3K activated.

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 Council on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed; in particular, those affording greater protection to the safety of study participants.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 2
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	Japan: 12
Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	Spain: 22
Country: Number of subjects enrolled	United States: 14
Worldwide total number of subjects	67
EEA total number of subjects	24

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)	29
From 65 to 84 years	37
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 6 centers in Australia, Canada, Japan, Poland, Spain and the United States. All enrolled participants from 6 centers were included in the trial.

Pre-assignment

Screening details:

This study was conducted in parallel-arms in adult participants with recurrent endometrial cancer. Randomized arms included PF-05212384 (154mg dosage) and PF-04691502 (8mg which was lowered to 6mg) for both PI3K Basal or Activated. Lead-in Cohorts included PF-05212384 (89mg or 154mg) and PF-04691502 (4mg).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	PF-04691502 8 mg (PI3K Basal)

Arm description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants self-administered PF-04691502 8 mg orally, once daily (QD) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death. Dose of the participants were reduced to 6 mg if they were on 8 mg dose.

Arm type	Experimental
Investigational medicinal product name	PF-04691502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants self-administered PF-04691502 8 mg orally, once daily (QD) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Investigational medicinal product name	PF-04691502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received PF-04691502 8 mg by 30 minute infusion at the study site, once weekly (Quaque, QW) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm title	PF-04691502 6 mg (PI3K Basal)

Arm description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm type	Experimental

Investigational medicinal product name	PF-04691502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm title	PF-04691502 8 mg (PI3K Activated)

Arm description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants self-administered PF-04691502 8 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death. Dose of the participants were reduced to 6 mg if they were on 8 mg dose.

Arm type	Experimental
Investigational medicinal product name	PF-04691502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants self-administered PF-04691502 8 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death. Dose of the participants were reduced to 6 mg if they were on 8 mg dose.

Arm title	PF-04691502 6 mg (PI3K Activated)

Arm description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	PF-04691502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm title	PF-05212384 154 mg (PI3K Basal)

Arm description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants received PF-05212384 154 mg by 30 minute infusion at the study site, once weekly (Quaque, QW) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	PF-05212384
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received PF-05212384 154 mg by 30 minute infusion at the study site, once weekly (Quaque, QW) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm title	PF-05212384 154 mg (PI3K Activated)

Arm description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants received PF-05212384 154 mg by 30 minute infusion at the study site, QW until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	PF-05212384
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received PF-05212384 154 mg by 30 minute infusion at the study site, QW until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm title	Lead-in-cohort (LIC) PF-04691502 (4 mg)

Arm description:

Participants who were enrolled in the PF-04691502 LIC began dosing with PF-04691502 4 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05691502 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	PF-04691502
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants who were enrolled in the PF-04691502 LIC began dosing with PF-04691502 4 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05691502 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm title	LIC PF-05212384 (89 mg)

Arm description:

Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 89 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm type	Experimental
Investigational medicinal product name	PF-05212384
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Oral use

Dosage and administration details:

Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 89 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm title	LIC PF-05212384 (154 mg)

Arm description:

Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 154 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Arm type	Experimental

Investigational medicinal product name	05212384
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Oral use

Dosage and administration details:

Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 154 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until hey experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Number of subjects in period 1	PF-04691502 8 mg (PI3K Basal)	PF-04691502 6 mg (PI3K Basal)	PF-04691502 8 mg (PI3K Activated)
Started	3	1	11
Completed	0	0	0
Not completed	3	1	11
Other Reasons	-	-	1
Death	1	-	8
Study Terminated by Sponsor	2	1	1
Lost to follow-up	-	-	-
Subject Refused Futher Follow-up	-	-	1

Number of subjects in period 1	PF-04691502 6 mg (PI3K Activated)	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)
Started	3	20	20
Completed	0	0	0
Not completed	3	20	20
Other Reasons	-	-	-
Death	-	7	12
Study Terminated by Sponsor	3	11	7
Lost to follow-up	-	1	1
Subject Refused Futher Follow-up	-	1	-

Number of subjects in period 1	Lead-in-cohort (LIC) PF-04691502 (4 mg)	LIC PF-05212384 (89 mg)	LIC PF-05212384 (154 mg)
Started	3	3	3
Completed	0	0	0
Not completed	3	3	3
Other Reasons	-	-	-
Death	-	1	1
Study Terminated by Sponsor	3	2	2
Lost to follow-up	-	-	-
Subject Refused Futher Follow-up	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	PF-04691502 8 mg (PI3K Basal)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants self-administered PF-04691502 8 mg orally, once daily (QD) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death. Dose of the participants were reduced to 6 mg if they were on 8 mg dose.

Reporting group title	PF-04691502 6 mg (PI3K Basal)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	PF-04691502 8 mg (PI3K Activated)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants self-administered PF-04691502 8 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death. Dose of the participants were reduced to 6 mg if they were on 8 mg dose.

Reporting group title	PF-04691502 6 mg (PI3K Activated)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	PF-05212384 154 mg (PI3K Basal)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants received PF-05212384 154 mg by 30 minute infusion at the study site, once weekly (Quaque, QW) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	PF-05212384 154 mg (PI3K Activated)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants received PF-05212384 154 mg by 30 minute infusion at the study site, QW until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	Lead-in-cohort (LIC) PF-04691502 (4 mg)

Reporting group description:

Participants who were enrolled in the PF-04691502 LIC began dosing with PF-04691502 4 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05691502 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	LIC PF-05212384 (89 mg)

Reporting group description:

Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 89 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	LIC PF-05212384 (154 mg)

Reporting group description:

Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 154 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group values	PF-04691502 8 mg (PI3K Basal)	PF-04691502 6 mg (PI3K Basal)	PF-04691502 8 mg (PI3K Activated)
Number of subjects	3	1	11
Age Categorical Units: Subjects			
< 18 years	0	0	0
18 - 44 years	0	0	0
45 - 64 years	2	1	4
>= 65 years	1	0	7
Age continuous Units: years			
arithmetic mean	3	1	11
standard deviation	± 61.7	± 54	± 66.5
Gender, Male/Female Units: Subjects			
Female	3	1	11
Male	0	0	0

Reporting group values	PF-04691502 6 mg (PI3K Activated)	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)
Number of subjects	3	20	20
Age Categorical Units: Subjects			
< 18 years	0	0	0
18 - 44 years	0	0	0
45 - 64 years	3	9	4
>= 65 years	0	11	16
Age continuous Units: years			
arithmetic mean	3	20	20
standard deviation	± 60	± 65.7	± 69.6
Gender, Male/Female Units: Subjects			
Female	3	20	20
Male	0	0	0

Reporting group values	Lead-in-cohort (LIC) PF-04691502 (4 mg)	LIC PF-05212384 (89 mg)	LIC PF-05212384 (154 mg)
Number of subjects	3	3	3
Age Categorical Units: Subjects			
< 18 years	0	0	0
18 - 44 years	0	1	0
45 - 64 years	2	1	2
>= 65 years	1	1	1
Age continuous Units: years			
arithmetic mean	3	3	3
standard deviation	± 64.3	± 56.7	± 62.7
Gender, Male/Female Units: Subjects			
Female	3	3	3

Male	0	0	0

Reporting group values	Total		
Number of subjects	67		
Age Categorical Units: Subjects			
< 18 years	0		
18 - 44 years	1		
45 - 64 years	28		
>= 65 years	38		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female Units: Subjects			
Female	67		
Male	0		

End points

End points reporting groups

Reporting group title	PF-04691502 8 mg (PI3K Basal)
Reporting group description:	
Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants self-administered PF-04691502 8 mg orally, once daily (QD) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death. Dose of the participants were reduced to 6 mg if they were on 8 mg dose.	
Reporting group title	PF-04691502 6 mg (PI3K Basal)
Reporting group description:	
Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.	
Reporting group title	PF-04691502 8 mg (PI3K Activated)
Reporting group description:	
Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants self-administered PF-04691502 8 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death. Dose of the participants were reduced to 6 mg if they were on 8 mg dose.	
Reporting group title	PF-04691502 6 mg (PI3K Activated)
Reporting group description:	
Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.	
Reporting group title	PF-05212384 154 mg (PI3K Basal)
Reporting group description:	
Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants received PF-05212384 154 mg by 30 minute infusion at the study site, once weekly (Quaque, QW) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.	
Reporting group title	PF-05212384 154 mg (PI3K Activated)
Reporting group description:	
Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants received PF-05212384 154 mg by 30 minute infusion at the study site, QW until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.	
Reporting group title	Lead-in-cohort (LIC) PF-04691502 (4 mg)
Reporting group description:	
Participants who were enrolled in the PF-04691502 LIC began dosing with PF-04691502 4 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05691502 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.	
Reporting group title	LIC PF-05212384 (89 mg)
Reporting group description:	
Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 89 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.	
Reporting group title	LIC PF-05212384 (154 mg)
Reporting group description:	
Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 154 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.	
Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants were analyzed on safety analysis set which was defined as all enrolled patients who started treatment.

Subject analysis set title	Per Protocol Set
Subject analysis set type	Per protocol

Subject analysis set description:

Per protocol dataset included participants enrolled for treatment, with baseline tumor, measurable disease and with disease under study. The LIC eporting arm were not a part of the per protocol analysis set for summarizing response.

Subject analysis set title	Pharmacokinetics Analysis Set
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects were analyzed on PK parameter analysis set which was defined as all treated patients who had at least one of the PK parameters of interest estimated.

Subject analysis set title	Pharmacodynamic Analysis Biomarkers Set
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects were analyzed on PD analysis set which consisted of all enrolled patients who started treatment and had a baseline as well as at least one post-baseline measurement for at least one PD biomarker. The PD biomarkers include serum glucose, insulin, HbA1c, cholesterol, and triglycerides.

Subject analysis set title	Molecular Profiling Tumor Analysis Set
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects were analyzed as the molecular profiling tumor analysis set was defined as all enrolled patients who started treatment and had baseline tumor tissues (archived paraffin block or unstained slides or fresh tumor tissue sample) successfully analyzed for at least one of the biomarkers.

Subject analysis set title	PF-05212384 (PI3K Basal + Activated)
Subject analysis set type	Per protocol

Subject analysis set description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal + activated). Participants were given PF-05212384 QW (Days 1, 8, 15 and 22 of each cycle), with a ±3 day window.

Subject analysis set title	PF-04691502 (PI3K Basal)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants self-administered PF-04691502 orally, once daily (QD) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Subject analysis set title	PF-04691502 (PI3K Activated)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants self-administered PF-04691502 8 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Primary: Clinical Benefit Response for PF-04691502

End point title	Clinical Benefit Response for PF-04691502[1]

End point description:

Clinical benefit response was defined as best overall response of complete response (CR), partial response (PR) or stable disease (SD) for at least 16 weeks from Cycle 1 Day 1 (C1D1) to the first time of disease progression. The outcome data table below presents the number of participants with clinical benefit response as "yes" or "no". On 09 Oct 2012, Pfizer decided to stop enrollment into PF-04691502. While tumor assessment for PF-04691502 was included as a listing in the final report, formal efficacy analysis for PF-04691502 was not performed.
Per protocol dataset included participants enrolled for treatment, with baseline tumor, measurable disease and with disease under study. The LIC reporting arm were not a part of the per protocol analysis set for summarizing response.

End point type	Primary

End point timeframe:

16 weeks from Cycle 1 Day 1

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint has no statistical analysis.

End point values	PF-04691502 (PI3K Basal)	PF-04691502 (PI3K Activated)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	11		
Units: Participants				
Participants with "Yes" response	1	0		
Participants with "No" response	3	11		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants with clinical benefit response for PF-05212384

End point title	Percentage of participants with clinical benefit response for PF-05212384[2][3]

End point description:

Clinical benefit response was defined as best overall response of complete response (CR), partial response (PR) or stable disease (SD) for at least 16 weeks from Cycle 1 Day 1 (C1D1) to the first time of disease progression. The primary analysis is based on the clinical benefit rate which is calculated as proportion of participants with a clinical benefit response relative to total number of response evaluable participants. Per RECIST v1.1 for target lesions: CR defined as disappearance of all target lesions; PR defined as >=30% decrease in the sum of the longest diameter of target lesions; SD does not qualify for CR, PR or Progression. All target lesions must be assessed. SD can follow PR only in the rare case that the sum increases by less than 20% from the nadir, but enough that a previously documented 30% decrease no longer holds. A Clopper-Pearson exact 95% CI for the clinical benefit rate is presented in the below table.

End point type	Primary

End point timeframe:

16 weeks from Cycle 1 Day 1

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint has no statistical analysis.

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	10	5	15	
Units: Percentage of participants				
number (confidence interval 95%)	52.6 (28.9 to 75.6)	26.3 (9.1 to 51.2)	39.5 (24 to 56.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response for PF-04691502

End point title	Objective Response for PF-04691502

End point description:

Objective response is defined as CR or PR. CR: Complete response: 2 or more objective statuses of CR a minimum of 4 weeks apart documented before PD. Partial response: 2 or more objective statuses of PR or better a minimum of 4 weeks apart documented before PD, but not qualifying as CR. Per RECIST v1.1 for target lesions: CR defined as disappearance of all target lesions; PR defined as >=30% decrease in the sum of the longest diameter of target lesions. The outcome data table below presents the number of participants with objective response as "yes" or "no". On 09 Oct 2012, Pfizer decided to stop enrollment into PF-04691502. While tumor assessment for PF-04691502 was included as a listing in the final report, formal efficacy analysis for PF-04691502 was not performed.
The LIC reporting arm were not a part of the per protocol analysis set for summarizing response.

End point type	Secondary

End point timeframe:

Randomization to objective progression, death or last tumor assessment without progression (up to 12 months)

End point values	PF-04691502 (PI3K Basal)	PF-04691502 (PI3K Activated)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	11		
Units: Participants response				
Participants with "Yes" response	0	0		
Participants with "No" response	4	11		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with objective response for PF-05212384

End point title	Percentage of participants with objective response for PF-05212384[4]

End point description:

Objective response is defined as CR or PR. CR: Complete response: 2 or more objective statuses of CR a minimum of 4 weeks apart documented before PD. Partial response: 2 or more objective statuses of PR or better a minimum of 4 weeks apart documented before PD, but not qualifying as CR. Per RECIST v1.1 for target lesions: CR defined as disappearance of all target lesions; PR defined as >=30% decrease in the sum of the longest diameter of target lesions.
The LIC reporting arm were not a part of the per protocol analysis set for summarizing response.

End point type	Secondary

End point timeframe:

Randomization to objective progression, death or last tumor assessment without progression (up to 12 months)

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	19	38	
Units: Percentage of participants				
number (confidence interval 95%)	21.1 (6.1 to 45.6)	15.8 (3.4 to 39.6)	18.4 (7.7 to 34.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression free survival for PF-04691502

End point title	Progression free survival for PF-04691502

End point description:

PFS is defined as the time from the date of cycle 1 day 1 to the date that objective progressive disease is documented or death due to any cause, whichever occurs first. PFS was characterized in terms of the median. Approximate 95% confidence interval corresponding to this estimate was computed.
Progression is defined using RECIST v1.1, as a 20% increase in the sum of the longest diameter of target lesions with a minimum absolute increase of 5 mm, or an unequivocal progression of non-target lesion, or the appearance of new lesions. On 09 Oct 2012, Pfizer decided to stop enrollment into PF-04691502. While tumor assessment for PF-04691502 was included as a listing in the final report, formal efficacy analysis for PF-04691502 was not performed.
The LIC reporting arm were not a part of the per protocol analysis set for summarizing response.

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to objective progressive disease or death due to any cause whichever occurs first (up to 12 months)

End point values	PF-04691502 (PI3K Basal)	PF-04691502 (PI3K Activated)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	11		
Units: Time to Event (Days)				
Participant 1	1	0		
Participant 2	108	0		
Participant 3	50	0		
Participant 4	199	0		
Participant 5	0	54		
Participant 6	0	55		

Participant 7	0	51		
Participant 8	0	1		
Participant 9	0	54		
Participant 10	0	62		
Participant 11	0	53		
Participant 12	0	105		
Participant 13	0	1		
Participant 14	0	54		
Participant 15	0	54		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression free survival for PF-05212384

End point title	Progression free survival for PF-05212384[5]

End point description:

PFS is defined as the time from the date of cycle 1 day 1 to the date that objective progressive disease is documented or death due to any cause, whichever occurs first. PFS was characterized in terms of the median. Approximate 95% confidence interval corresponding to this estimate was computed.
Progression is defined using RECIST v1.1, as a 20% increase in the sum of the longest diameter of target lesions with a minimum absolute increase of 5 mm, or an unequivocal progression of non-target lesion, or the appearance of new lesions.
The LIC reporting arm were not a part of the per protocol analysis set for summarizing response.

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to objective progressive disease or death due to any cause whichever occurs first (up to 12 months)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	19	38	
Units: Days				
median (confidence interval 95%)	112 (59 to 167)	89 (56 to 172)	108 (62 to 149)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with progression free survival (PFS) at 6 months for PF-05212384

End point title	Percentage of participants with progression free survival (PFS) at 6 months for PF-05212384[6]

End point description:

Progression free survival is defined as the time from the date of cycle 1 day 1 to the date that objective progressive disease is documented or death due to any cause, whichever occurs first. PFS was characterized in terms of the probability of remaining progression-free at 6 months (based on Kaplan-Meier estimates). Progression is defined using RECIST v1.1, as a 20% increase in the sum of the longest diameter of target lesions with a minimum absolute increase of 5 mm, or an unequivocal progression of non-target lesion, or the appearance of new lesions.
Per protocol dataset included participants enrolled for treatment, with baseline tumor, measurable disease and with disease under study.
The LIC reporting arm were not a part of the per protocol analysis set for summarizing response.

End point type	Secondary

End point timeframe:

6 months

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	19	38	
Units: Percentage of participants				
number (confidence interval 95%)	23.2 (7.3 to 44.1)	25 (7.8 to 47.2)	24.3 (11.6 to 39.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) for PF-05212384

End point title	Overall Survival (OS) for PF-05212384[7]

End point description:

OS is defined as the time from the date of Cycle 1 Day 1 to the date of death.
Survival analysis was not performed as the study was terminated early. No data are available because data were not collected. The LIC reporting arm were not a part of the per protocol analysis set for summarizing response.

End point type	Secondary

End point timeframe:

12 months

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	0[8]	0[9]	0[10]	
Units: Percentage of participants				

Notes:

[8] - Survival analysis was not performed as the study was terminated early. No data are available.

[9] - Survival analysis was not performed as the study was terminated early. No data are available.

[10] - Survival analysis was not performed as the study was terminated early. No data are available.

Statistical analyses

No statistical analyses for this end point

Secondary: Level of each pharmacodynamic parameter at specified timepoints- Glucose (mg/dL)

End point title	Level of each pharmacodynamic parameter at specified timepoints- Glucose (mg/dL)[11]

End point description:

PD biomarkers are measured at screening (baseline) and multiple time points post baseline. Baseline is defined as the last measurement prior to dosing, which is the measurement at screening or the cycle 1 day 1 pre-dose measurement if collected. Subjects were analyzed on PD analysis set which consisted of all enrolled patients who started treatment and had a baseline as well as at least one post-baseline measurement for at least one PD biomarker. The PD biomarkers include serum glucose, insulin, HbA1c, cholesterol, and triglycerides.

End point type	Secondary

End point timeframe:

Baseline (Day -3) and Cycle1 to Cycle 5 where each cycle consist of 28 days

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	18	18	36	
Units: Glucose (mg/dL)				
arithmetic mean (standard deviation)				
Baseline	98.5 (± 12.76)	101.7 (± 26.56)	100.1 (± 20.6)	
Cycle 1 Day 15 (n=18,17,35)	105.3 (± 18.44)	117.2 (± 61.04)	111.1 (± 44.26)	
Cycle 1 Day 22 (n=2,1,3)	103 (± 19.31)	114 (± 39.42)	108.7 (± 15.19)	
Cycle 2 Day 1 (n=17,14,31)	103.7 (± 19.31)	114 (± 39.42)	108.3 (± 29.99)	
Cycle 2 Day 15 (n=17,8,25)	104.8 (± 13.94)	106.4 (± 19.36)	105.3 (± 15.47)	
Cycle 3 Day 1 (n=14,10,24)	100.6 (± 16.29)	125.9 (± 74.5)	111.1 (± 49.85)	
Cycle 4 Day 1 (n=12,7,19)	96.3 (± 10.4)	98.9 (± 10.2)	97.3 (± 10.12)	
Cycle 5 Day 1 (n=9,4,13)	103.2 (± 15.17)	112.2 (± 24.37)	106 (± 17.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Level of each pharmacodynamic parameter at specified timepoints- Insulin (UIU/mL)

End point title	Level of each pharmacodynamic parameter at specified timepoints- Insulin (UIU/mL)[12]

End point description:

PD biomarkers are measured at screening (baseline) and multiple time points post baseline. Baseline is defined as the last measurement prior to dosing, which is the measurement at screening or the cycle 1 day 1 pre-dose measurement if collected. Subjects were analyzed on PD analysis set which consisted of all enrolled patients who started treatment and had a baseline as well as at least one ost-baseline measurement for at least one PD biomarker. The PD biomarkers include serum glucose, insulin, HbA1c, cholesterol, and triglycerides.

End point type	Secondary

End point timeframe:

Baseline (Day -3) and Cycle1 to Cycle 5 where each cycle consist of 28 days

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	17	14	31	
Units: Insulin (UIU/mL)				
arithmetic mean (standard deviation)				
Baseline	15.2 (± 12.68)	14.4 (± 7.03)	14.8 (± 10.36)	
Cycle 1 Day 15 (n=16,12,28)	23.6 (± 14.69)	35.9 (± 37.05)	28.9 (± 26.79)	
Cycle 1 Day 22 (n=2,1,3)	57.6 (± 51.18)	29.1 (± 0)	48.1 (± 39.75)	
Cycle 2 Day 1 (n=17,10,27)	30.3 (± 28.92)	28.9 (± 27.85)	29.8 (± 27.99)	
Cycle 2 Day 15 (n=14,6,20)	28.2 (± 29.56)	21.9 (± 10.49)	26.3 (± 25.21)	
Cycle 3 Day 1 (n=13,9,22)	20.7 (± 13.65)	35.1 (± 38.66)	26.6 (± 26.99)	
Cycle 4 Day 1 (n=11,6,17)	17.1 (± 10.04)	24.8 (± 32.32)	19.8 (± 20.1)	
Cycle 5 Day 1 (n=7,4,11)	17 (± 15.56)	15.7 (± 6.2)	16.5 (± 12.54)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in each treatment arm with gene and/or protein expression biomarkers in biopsied tumor tissue- Summary of Biomarkers - Molecular Profiling Tumor Analysis Set: Stathmin H Score (N)

End point title	Percentage of participants in each treatment arm with gene and/or protein expression biomarkers in biopsied tumor tissue- Summary of Biomarkers - Molecular Profiling Tumor Analysis Set: Stathmin H Score (N)[13]

End point description:

Gene and/or protein expression biomarkers in biopsied tumor tissue relating to PI3K and/or mTOR pathway activation, such as PIK3CA and PIK3R1 mutations, PTEN protein levels, and PIK3CA gene

amplification were to be assessed.
Subjects were analyzed as the molecular profiling tumor analysis set was defined as all enrolled patients who started treatment and had baseline tumor tissues (archived paraffin block or unstained slides or fresh tumor tissue sample) successfully analyzed for at least one of the biomarkers.

End point type	Secondary

End point timeframe:

Baseline and Cycle1 to Cycle 5 where each cycle consist of 28 days

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	19	40	
Units: Score				
arithmetic mean (standard deviation)	96.4 (± 33.76)	201.3 (± 34.87)	146.2 (± 62.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in each treatment arm with gene and/or protein expression biomarkers- PIK3CA Amplification, KRAS Mutation P/N, KRAS Mutation OBSV, PTEN Stroma Manual Score, PTEN Tumor Manual Score, KRAS SCC and Stathmin H/L,Tissue.

End point title	Percentage of participants in each treatment arm with gene and/or protein expression biomarkers- PIK3CA Amplification, KRAS Mutation P/N, KRAS Mutation OBSV, PTEN Stroma Manual Score, PTEN Tumor Manual Score, KRAS SCC and Stathmin H/L,Tissue.[14]

End point description:

Gene and/or protein expression biomarkers in biopsied tumor tissue relating to PI3K and/or mTOR pathway activation, such as PIK3CA and PIK3R1 mutations, PTEN protein levels, and PIK3CA gene amplification were to be assessed.
Subjects were analyzed as the molecular profiling tumor analysis set was defined as all enrolled patients who started treatment and had baseline tumor tissues (archived paraffin block or unstained slides or fresh tumor tissue sample) successfully analyzed for at least one of the biomarkers.

End point type	Secondary

End point timeframe:

Baseline and Cycle 1 to Cycle 5 where each cycle consist of 28 days

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	20[15]	20[16]	40	
Units: Percentage				
number (not applicable)				
PIK3CA Amplification, Amplified (n=17,15,32)	5.9	6.7	6.3	
PIK3CA Amplification, Nonamplified (n=17,15,32)	94.1	93.3	93.8	
KRAS Mutation, Positive (n=21,18,39)	19	5.6	12.8	
KRAS Mutation, Negative (n=21,18,39)	81	94.4	87.2	
KRAS Mutation OBSV, Gly12Asp (n=4,1,5)	25	100	40	
KRAS Mutation OBSV, Gly12Cys (n=4,1,5)	25	0	20	
KRAS Mutation OBSV, Gly12Val (n=4,1,5)	50	0	40	
PTEN Stroma Manual Score, 1+ (n=21,19,40)	4.8	0	2.5	
PTEN Stroma Manual Score, 2+ (n=21,19,40)	28.6	26.3	27.5	
PTEN Stroma Manual Score, 3+ (n=21,19,40)	66.7	73.7	70	
PTEN Tumor Manual Score, 0 (n=21,19,40)	23.8	21.1	22.5	
PTEN Tumor Manual Score, 1+ (n=21,19,40)	38.1	31.6	35	
PTEN Tumor Manual Score, 2+ (n=21,19,40)	38.1	47.4	42.5	
KRAS SCC, Acceptable (n=21,18,39)	100	100	100	
Stathmin H/L,Tissue, High (n=21,19,40)	0	100	47.5	
Stathmin H/L,Tissue, Low (n=21,19,40)	100	0	52.5	

Notes:

[15] - N=21
One subject had the stathmin status changed and was categorized under Basal.
[16] - N= 19
One subject had their stathmin status changed and was categorized under Basal.

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the serum concentration time profile from time zero extrapolated to infinity (AUCinf) of PF-05212384 at each specified time points.

End point title	Area under the serum concentration time profile from time zero extrapolated to infinity (AUCinf) of PF-05212384 at each specified time points.[17]

End point description:

AUCinf of PF-05212384 at each specified time points. Subjects were analyzed on PK parameter analysis set which was defined as all treated patients who had at least one of the PK parameters of interest estimated.

End point type	Secondary

End point timeframe:

From Day 1 until 35 days post last dose

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	15		
Units: ng.hr/mL				
geometric mean (geometric coefficient of variation)	15280 (± 24)	14870 (± 40)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the serum concentration time profile from time zero to the time of the last quantifiable concentration (AUClast) of PF-05212384 at each specified time points.

End point title	Area under the serum concentration time profile from time zero to the time of the last quantifiable concentration (AUClast) of PF-05212384 at each specified time points.[18]

End point description:

AUClast of PF-05212384 at each specified time points.
Subjects were analyzed on PK parameter analysis set which was defined as all treated patients who had at least one of the PK parameters of interest estimated.

End point type	Secondary

End point timeframe:

From Day 1 until 35 days post last dose

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	15		
Units: ng.hr/mL				
geometric mean (geometric coefficient of variation)	15080 (± 24)	15890 (± 52)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum plasma concentration (Cmax) of PF-05212384 at each specified time points.

End point title	Maximum plasma concentration (Cmax) of PF-05212384 at each specified time points.[19]

End point description:

Cmax of PF-05212384 at each specified time points.
Subjects were analyzed on PK parameter analysis set which was defined as all treated patients who had at least one of the PK parameters of interest estimated.

End point type	Secondary

End point timeframe:

From Day 1 until 35 days post last dose

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	15		
Units: ng/mL				
geometric mean (geometric coefficient of variation)	9078 (± 36)	7057 (± 84)		

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal elimination half life (t½) of PF-05212384 at each specified time points.

End point title	Terminal elimination half life (t½) of PF-05212384 at each specified time points.[20]

End point description:

t½ of PF-05212384 at each specified time points.
Subjects were analyzed on PK parameter analysis set which was defined as all treated patients who had at least one of the PK parameters of interest estimated.

End point type	Secondary

End point timeframe:

From Day 1 until 35 days post last dose

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	15		
Units: hr				
arithmetic mean (standard deviation)	35.02 (± 5.32)	34.09 (± 8.87)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time for Cmax (Tmax) of PF-05212384 at each specified time points.

End point title	Time for Cmax (Tmax) of PF-05212384 at each specified time points.[21]

End point description:

Tmax of PF-05212384 at each specified time points.
Subjects were analyzed on PK parameter analysis set which was defined as all treated patients who had at least one of the PK parameters of interest estimated.

End point type	Secondary

End point timeframe:

From Day 1 until 35 days post last dose

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	15		
Units: hr				
median (full range (min-max))	0.525 (0.5 to 1.07)	0.65 (0.5 to 1.08)		

Statistical analyses

No statistical analyses for this end point

Secondary: Clearance (CL) of PF-05212384 at each specified time points.

End point title	Clearance (CL) of PF-05212384 at each specified time

End point description:

End point type	Secondary

End point timeframe:

From Day 1 until 35 days post last dose

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	15		
Units: L/hr				
geometric mean (geometric coefficient of variation)	10.09 (± 24)	10.36 (± 40)		

Statistical analyses

No statistical analyses for this end point

Secondary: Steady state volume of distribution (Vss) of PF-05212384 at each specified time points.

End point title	Steady state volume of distribution (Vss) of PF-05212384 at each specified time points.[23]

End point description:

End point type	Secondary

End point timeframe:

Day 1 to Day 5

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	15		
Units: Litres				
geometric mean (geometric coefficient of variation)	165.6 (± 32)	174.9 (± 57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of treatment-emergent adverse events (TEAEs) - all causalities

End point title	Summary of treatment-emergent adverse events (TEAEs) - all causalities[24]

End point description:

Safety of participants in terms of TEAEs.

End point type	Secondary

End point timeframe:

From baseline (-3 days) until 35 days post last dose

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2	1	3	
Units: Participants				
Number of Adverse Events (AEs)	10	6	16	
Participants with AEs	2	1	3	
Participants with Serious Adverse Events (SAEs)	0	0	0	
Participants with Grade 3 or Grade 4 AEs	1	1	2	
Participants with Grade 5 AEs	0	0	0	
Permanently Discontinued due to AEs	1	1	2	
Dose Reduced due to AEs	0	0	0	
Temporary Discontinuations due to AEs	1	1	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of treatment-related TEAEs

End point title	Summary of treatment-related TEAEs[25]

End point description:

Safety of subject in terms of number of participants with treatment related AEs.

End point type	Secondary

End point timeframe:

From baseline (-3 days) until 35 days post last dose

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2	1	3	
Units: Participants				
Number of AEs	9	5	14	

Participants with AEs	2	1	3	
Participants with SAEs	0	0	0	
Participants with Grade 3 or Grade 4 AEs	1	1	2	
Participants with Grade 5 AEs	0	0	0	
Permanently Discontinued due to AEs	1	1	2	
Dose Reduced due to AEs	0	0	0	
Temporary Discontinuations due to AEs	1	1	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Level of each pharmacodynamic parameter at specified timepoints- Glycosylated Hemoglobin (HbA1c)

End point title	Level of each pharmacodynamic parameter at specified timepoints- Glycosylated Hemoglobin (HbA1c)[26]

End point description:

PD biomarkers are measured at screening (baseline) and multiple time points post baseline. Baseline is defined as the last measurement prior to dosing, which is the measurement at screening or the cycle 1 day 1 pre-dose measurement if collected.

End point type	Secondary

End point timeframe:

Baseline (Day -3) and Cycle1 to Cycle 5 where each cycle consist of 28 days

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	18	18	36	
Units: HbA1c				
arithmetic mean (standard deviation)				
Baseline (n=15,14,29)	7.8 (± 8.58)	7.5 (± 6.15)	7.7 (± 7.37)	
Cycle 1 Day 15 (n=4,2,6)	14.7 (± 19)	7.1 (± 1.34)	12.2 (± 15.25)	
Cycle 2 Day 1 (n=14,11,25)	1.08 (± 0.056)	1.13 (± 0.088)	1.1 (± 0.075)	
Cycle 2 Day 15 (n=3,0,3)	6.7 (± 0.71)	0 (± 0)	6.7 (± 0.71)	
Cycle 3 Day 1 (n=10,4,14)	6 (± 0.78)	7.3 (± 1.7)	6.4 (± 1.19)	
Cycle 4 Day 1 (n=12,7,19)	8.9 (± 10.13)	6.9 (± 1.05)	8.2 (± 8.01)	
Cycle 5 Day 1 (n=8,2,10)	5.9 (± 0.89)	31.5 (± 36.06)	11 (± 16.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Level of each pharmacodynamic parameter at specified timepoints- Cholesterol (mg/dL)

End point title	Level of each pharmacodynamic parameter at specified timepoints- Cholesterol (mg/dL)[27]

End point description:

PD biomarkers are measured at screening (baseline) and multiple time points post baseline. Baseline is defined as the last measurement prior to dosing, which is the measurement at screening or the cycle 1 day 1 pre-dose measurement if collected.
Subjects were analyzed on PD analysis set which consisted of all enrolled patients who started treatment and had a baseline as well as at least one post-baseline measurement for at least one PD biomarker.

End point type	Secondary

End point timeframe:

Baseline (Day -3) and Cycle 1 to Cycle 3 where each cycle consist of 28 days

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	18	18	36	
Units: Cholesterol (mg/dL)				
arithmetic mean (standard deviation)				
Baseline (n=11,4,15)	213 (± 54.48)	186.5 (± 52.43)	205.9 (± 53.45)	
Cycle 1 Day 28 (n=15,7,22)	214.9 (± 49.15)	161.6 (± 86.51)	198 (± 66.28)	
Cycle 2 Day 22 (n=16,6,22)	229.8 (± 44.31)	127.9 (± 108.69)	202 (± 79.83)	
Cycle 3 Day 28 (n=11,4,15)	230.5 (± 48.63)	137.6 (± 107.02)	205.7 (± 77.15)	

Statistical analyses

No statistical analyses for this end point

Secondary: Level of each pharmacodynamic parameter at specified timepoints- Triglycerides (mg/dL)

End point title	Level of each pharmacodynamic parameter at specified timepoints- Triglycerides (mg/dL)[28]

End point description:

PD biomarkers are measured at screening (baseline) and multiple time points post baseline. Baseline is defined as the last measurement prior to dosing, which is the measurement at screening or the cycle 1 day 1 pre-dose measurement if collected.

End point type	Secondary

End point timeframe:

Baseline (Day -3) and Cycle1 to Cycle 3 where each cycle consist of 28 days

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint has no statistical analysis.

End point values	PF-05212384 154 mg (PI3K Basal)	PF-05212384 154 mg (PI3K Activated)	PF-05212384 (PI3K Basal + Activated)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	18	18	36	
Units: Triglycerides (mg/dL)				
arithmetic mean (standard deviation)				
Baseline (n=11,4,15)	104.2 (± 40.95)	133.4 (± 25.75)	112 (± 38.96)	
Cycle 1 Day 28 (n=15,7,22)	136.9 (± 70.03)	134.5 (± 57.21)	136.1 (± 64.85)	
Cycle 2 Day 28 (n=16,6,22)	133.2 (± 71.4)	117.1 (± 62.77)	128.8 (± 68.07)	
Cycle 3 Day 28 (n=10,4,14)	119.9 (± 64.22)	130.4 (± 58.01)	122.9 (± 60.47)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Maximum of treatment duration (i.e., 21 to 169 days for the PF 04691502 [PI3K basal and activated], 29 to 345 days for PF 05212384 PI3K basal and 1 to 400 days for PF 05212384 PI3K activated) + 28 days across all participants.

Adverse event reporting additional description:

All causality AEs and SAEs are included in this section. The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one participant and as nonserious in another participant, or one participant may have experienced both a serious and nonserious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	PF-04691502 8 mg (PI3K Basal)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants self-administered PF-04691502 8 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death. Dose of the participants were reduced to 6 mg if they were on 8 mg dose.

Reporting group title	PF-04691502 6 mg (PI3K Basal)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	PF-04691502 8 mg (PI3K Activated)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants self-administered PF-04691502 8 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death. Dose of the participants were reduced to 6 mg if they were on 8 mg dose.

Reporting group title	PF-04691502 6 mg (PI3K Activated)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants self-administered PF-04691502 6 mg orally, QD until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	PF-05212384 154 mg (PI3K Basal)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K basal). Participants received PF-05212384 154 mg by 30 minute infusion at the study site, QW (Quaque [Once Weekly]) until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	Lead-in-cohort (LIC) PF-04691502 (4 mg)

Reporting group description:

Participants who were enrolled in the PF-04691502 LIC began dosing with PF-04691502 4 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05691502 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	PF-05212384 154 mg (PI3K Activated)

Reporting group description:

Eligible participants were categorized by PI3K pathway activation status (i.e. PI3K activated). Participants received PF-05212384 154 mg by 30 minute infusion at the study site, QW until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	LIC PF-05212384 (89 mg)

Reporting group description:

Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 89 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Reporting group title	LIC PF-05212384 (154 mg)

Reporting group description:

Participants who were enrolled in the PF-05212384 LIC began dosing with PF-05212384 154 mg at least 4 days (but no more than 10 days) prior to Cycle 1 Day 1 and continued taking PF-05212384 until they experienced unacceptable toxicity, disease progression, significant deviation, withdrawal of consent or death.

Serious adverse events	PF-04691502 8 mg (PI3K Basal)	PF-04691502 6 mg (PI3K Basal)	PF-04691502 8 mg (PI3K Activated)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	1 / 1 (100.00%)	7 / 9 (77.78%)
number of deaths (all causes)	3	0	6
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastric Cancer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
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			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
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			
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease Progression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Acute Respiratory Distress Syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pneumonitis			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences causally related to treatment / all	2 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax Spontaneous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
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			
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
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			
Cardiac Failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular Accident			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
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			
Diarrhoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral Pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 1 (100.00%)	0 / 9 (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
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 1 (100.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			

subjects affected / exposed	0 / 5 (0.00%)	1 / 1 (100.00%)	0 / 9 (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
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
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 Obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
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			
Lung Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyelonephritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
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 Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-04691502 6 mg (PI3K Activated)	PF-05212384 154 mg (PI3K Basal)	Lead-in-cohort (LIC) PF-04691502 (4 mg)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	3 / 21 (14.29%)	1 / 3 (33.33%)
number of deaths (all causes)	0	8	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastric Cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
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			
Deep Vein Thrombosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
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			
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease Progression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (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
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Distress Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax Spontaneous			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	0 / 3 (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 Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
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			
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	7 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac Failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular Accident			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (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			
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
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			
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
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 Obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (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
Fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
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			
Lung Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
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 Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
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	PF-05212384 154 mg (PI3K Activated)	LIC PF-05212384 (89 mg)	LIC PF-05212384 (154 mg)
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 19 (52.63%)	0 / 3 (0.00%)	1 / 3 (33.33%)
number of deaths (all causes)	11	1	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastric Cancer			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (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
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (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
Disease Progression			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Distress Syndrome			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax Spontaneous			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Cardiac Failure			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (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			
Cerebrovascular Accident			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Diarrhoea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			

subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral Pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Dermatitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (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
Urinary Tract Obstruction			

subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (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
Infections and infestations			
Lung Infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (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
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (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
Skin Infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary Tract Infection			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	PF-04691502 8 mg (PI3K Basal)	PF-04691502 6 mg (PI3K Basal)	PF-04691502 8 mg (PI3K Activated)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	1 / 1 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oncologic Complication			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hot Flush			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Phlebitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	5
Catheter Site Bruise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter Site Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter Site Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Fatigue			
subjects affected / exposed	3 / 5 (60.00%)	0 / 1 (0.00%)	6 / 9 (66.67%)
occurrences (all)	4	0	13
Gait Disturbance			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Influenza Like Illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion Site Extravasation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion Site Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Medical Device Complication			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal Dryness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	6	0	4
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	3
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vulvovaginal Discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Dyspnoea Exertional			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleural Effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Productive Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Rhinalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper-Airway Cough Syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleurisy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bradyphrenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Confusional State			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Delirium			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysthymic Disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hallucination, Visual			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood Alkaline Phosphatase			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood Alkaline Phosphatase Increased			

subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Blood Cholesterol Increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood Magnesium Decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood Pressure Diastolic Increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest X-Ray Abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram Qt Prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	3
Glycosylated Haemoglobin Increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haemoglobin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Neutrophil Count Decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 1 (100.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Platelet Count Decreased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 1 (100.00%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Weight Decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 1 (100.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood Creatinine Increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion Related Reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pelvic Fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular Access Complication			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Amnesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Dysgeusia			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 1 (100.00%)	1 / 9 (11.11%)
occurrences (all)	0	1	2
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
External Ear Inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Abnormal Sensation In Eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eyelid Bleeding			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Iritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Visual Impairment			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dry Eyes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aphthous Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Cheilitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Constipation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	1	0	3
Diarrhoea			
subjects affected / exposed	4 / 5 (80.00%)	0 / 1 (0.00%)	7 / 9 (77.78%)
occurrences (all)	5	0	18
Dry Mouth			
subjects affected / exposed	1 / 5 (20.00%)	1 / 1 (100.00%)	2 / 9 (22.22%)
occurrences (all)	1	1	2
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hyperchlorhydria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia Oral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lip Ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Mouth Ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 5 (60.00%)	1 / 1 (100.00%)	5 / 9 (55.56%)
occurrences (all)	8	1	7
Odynophagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral Discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral Dysaesthesia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Oral Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rectal Haemorrhage			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	4 / 9 (44.44%)
occurrences (all)	1	0	6
Tooth Disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	3
Noninfective Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Hepatotoxicity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	3
Dermatitis Contact			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hangnail			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Ingrowing Nail			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nail Disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Night Sweats			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain Of Skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Palmar-Plantar Erythrodysaesthesia Syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Purpura			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	4	0	4
Rash Generalised			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-Papular			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Rash Papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin Disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Skin Exfoliation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Swelling Face			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 1 (100.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal Colic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Back Pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	3
Fistula			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Inguinal Mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Muscle Spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Candida Infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Folliculitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fungal Skin Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Genital Herpes Zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral Candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oral Fungal Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oral Herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Respiratory Tract Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Vulvitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	6 / 9 (66.67%)
occurrences (all)	2	0	6
Dehydration			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Diabetes Mellitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	5 / 5 (100.00%)	0 / 1 (0.00%)	7 / 9 (77.78%)
occurrences (all)	5	0	26
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Hypokalaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 1 (100.00%)	4 / 9 (44.44%)
occurrences (all)	1	2	5
Hypomagnesaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	4 / 9 (44.44%)
occurrences (all)	1	0	5
Hyponatraemia			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Hyperlipidaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PF-04691502 6 mg (PI3K Activated)	PF-05212384 154 mg (PI3K Basal)	Lead-in-cohort (LIC) PF-04691502 (4 mg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	21 / 21 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oncologic Complication			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tumour Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hot Flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	4 / 21 (19.05%)	0 / 3 (0.00%)
occurrences (all)	0	10	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	0 / 3 (0.00%)	7 / 21 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	10	0
Catheter Site Bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter Site Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter Site Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	5 / 21 (23.81%)	1 / 3 (33.33%)
occurrences (all)	3	5	1
Gait Disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infusion Site Extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Site Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	2 / 3 (66.67%)
occurrences (all)	0	11	4
Medical Device Complication			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Mucosal Dryness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
subjects affected / exposed	1 / 3 (33.33%)	12 / 21 (57.14%)	0 / 3 (0.00%)
occurrences (all)	3	22	0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Oedema Peripheral			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Pelvic Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Vulvovaginal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Catarrh			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	7 / 21 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	9	1
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	3 / 21 (14.29%)	1 / 3 (33.33%)
occurrences (all)	1	7	1
Dyspnoea Exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	18	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Pleural Effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Rhinalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-Airway Cough Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleurisy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Bradyphrenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Confusional State			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Dysthymic Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hallucination, Visual			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Alkaline Phosphatase			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Blood Creatinine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Magnesium Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Pressure Diastolic Increased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest X-Ray Abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram Qt Prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glycosylated Haemoglobin Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemoglobin			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Neutrophil Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Platelet Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	2 / 3 (66.67%)
occurrences (all)	0	4	3
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood Creatinine Increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	1 / 3 (33.33%)
occurrences (all)	0	4	1
Injury, poisoning and procedural			

complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Related Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic Fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vascular Access Complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Sinus Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Dysgeusia			
subjects affected / exposed	1 / 3 (33.33%)	6 / 21 (28.57%)	0 / 3 (0.00%)
occurrences (all)	1	7	0
Headache			
subjects affected / exposed	1 / 3 (33.33%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Leukopenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	4	0

Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
External Ear Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Abnormal Sensation In Eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid Bleeding			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Iritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vision Blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual Impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Eyes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Abdominal Distension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Abdominal Pain			

subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Abdominal Pain Upper			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Aphthous Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	7 / 21 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	8	2
Diarrhoea			
subjects affected / exposed	2 / 3 (66.67%)	8 / 21 (38.10%)	1 / 3 (33.33%)
occurrences (all)	3	10	2
Dry Mouth			
subjects affected / exposed	2 / 3 (66.67%)	3 / 21 (14.29%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperchlorhydria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia Oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip Ulceration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Mouth Ulceration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	12 / 21 (57.14%)	1 / 3 (33.33%)
occurrences (all)	1	19	1
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oral Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Oral Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Rectal Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	5 / 21 (23.81%)	1 / 3 (33.33%)
occurrences (all)	0	23	1
Tooth Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	7 / 21 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	12	1
Noninfective Gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Hepatotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dry Skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			

subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Hangnail			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ingrowing Nail			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail Disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Night Sweats			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Onycholysis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain Of Skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palmar-Plantar Erythrodysaesthesia Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Papule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0

Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 3 (33.33%)	6 / 21 (28.57%)	3 / 3 (100.00%)
occurrences (all)	1	9	6
Rash Generalised			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Rash Maculo-Papular			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Rash Papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Swelling Face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			

subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Renal Colic			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Urinary Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Back Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Fistula			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Inguinal Mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Myalgia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Osteopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain In Extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Fungal Skin Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Genital Herpes Zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	2	0

Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oral Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral Fungal Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral Herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	1 / 3 (33.33%)
occurrences (all)	0	1	5
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Skin Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Urinary Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	4	0

Vulvitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	1 / 3 (33.33%)	9 / 21 (42.86%)	0 / 3 (0.00%)
occurrences (all)	1	21	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diabetes Mellitus			
subjects affected / exposed	1 / 3 (33.33%)	1 / 21 (4.76%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 21 (9.52%)	0 / 3 (0.00%)
occurrences (all)	0	6	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 21 (19.05%)	2 / 3 (66.67%)
occurrences (all)	0	6	2
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 21 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 21 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 21 (4.76%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	PF-05212384 154 mg (PI3K Activated)	LIC PF-05212384 (89 mg)	LIC PF-05212384 (154 mg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 19 (94.74%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oncologic Complication			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour Pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot Flush			

subjects affected / exposed	1 / 19 (5.26%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypertension			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Lymphoedema			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pallor			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Catheter Site Bruise			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Catheter Site Oedema			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Catheter Site Pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fatigue			

subjects affected / exposed	10 / 19 (52.63%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	19	0	3
Gait Disturbance			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Site Extravasation			
subjects affected / exposed	0 / 19 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infusion Site Rash			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 19 (5.26%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	11	2	2
Medical Device Complication			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal Dryness			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Mucosal Inflammation			
subjects affected / exposed	8 / 19 (42.11%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	17	0	0
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Oedema Peripheral			
subjects affected / exposed	5 / 19 (26.32%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	7	1	0
Pain			

subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic Pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Discomfort			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 19 (15.79%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Dysphonia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	3 / 19 (15.79%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Dyspnoea Exertional			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Epistaxis			

subjects affected / exposed	2 / 19 (10.53%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	4	2	0
Haemoptysis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	3 / 19 (15.79%)	0 / 3 (0.00%)	3 / 3 (100.00%)
occurrences (all)	3	0	5
Pleural Effusion			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Productive Cough			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Upper-Airway Cough Syndrome			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pleurisy			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Bradyphrenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Confusional State			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Delirium			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Dysthymic Disorder			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination, Visual			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	3 / 19 (15.79%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Irritability			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	3
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	2
Blood Alkaline Phosphatase			

subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood Creatinine			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood Magnesium Decreased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood Pressure Diastolic Increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chest X-Ray Abnormal			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram Qt Prolonged			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glycosylated Haemoglobin Increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoglobin			

subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet Count Decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	3 / 19 (15.79%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	9	5	0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Fracture			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Infusion Related Reaction			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Limb Injury			

subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pelvic Fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular Access Complication			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Amnesia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	3 / 19 (15.79%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	1
Dysgeusia			
subjects affected / exposed	8 / 19 (42.11%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	27	0	2
Headache			
subjects affected / exposed	2 / 19 (10.53%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Hypersomnia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Somnolence			
subjects affected / exposed	4 / 19 (21.05%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Syncope			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Leukopenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
External Ear Inflammation			
subjects affected / exposed	0 / 19 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 19 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Eye disorders			

Abnormal Sensation In Eye			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Eyelid Bleeding			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iritis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Visual Impairment			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Eyes			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	4 / 19 (21.05%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	7	1	1
Abdominal Pain Lower			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain Upper			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Aphthous Stomatitis			

subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	6 / 19 (31.58%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	7	0	1
Diarrhoea			
subjects affected / exposed	10 / 19 (52.63%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	24	1	0
Dry Mouth			
subjects affected / exposed	4 / 19 (21.05%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Dyspepsia			
subjects affected / exposed	5 / 19 (26.32%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	9	1	0
Dysphagia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperchlorhydria			

subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia Oral			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Lip Ulceration			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth Ulceration			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	10 / 19 (52.63%)	3 / 3 (100.00%)	3 / 3 (100.00%)
occurrences (all)	24	8	5
Odynophagia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Oral Discomfort			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral Dysaesthesia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral Pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	2 / 19 (10.53%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Rectal Haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	3 / 19 (15.79%)	3 / 3 (100.00%)	3 / 3 (100.00%)
occurrences (all)	16	12	7
Tooth Disorder			

subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	7 / 19 (36.84%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	15	1	3
Noninfective Gingivitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatotoxicity			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	2 / 19 (10.53%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Eczema			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hangnail			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			

subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ingrowing Nail			
subjects affected / exposed	0 / 19 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nail Disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain Of Skin			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Palmar-Plantar Erythrodysaesthesia Syndrome			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Pruritus			
subjects affected / exposed	2 / 19 (10.53%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	9	5	2
Purpura			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	3 / 19 (15.79%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	4	17	2
Rash Generalised			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Rash Maculo-Papular			
subjects affected / exposed	5 / 19 (26.32%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	9	0	3
Rash Papular			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin Disorder			
subjects affected / exposed	0 / 19 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin Exfoliation			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin Lesion			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Swelling Face			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	3 / 19 (15.79%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Proteinuria			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Renal Colic			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Urinary Retention			

subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 19 (21.05%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	12	0	0
Back Pain			
subjects affected / exposed	3 / 19 (15.79%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Fistula			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inguinal Mass			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Osteopenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bacteriuria			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Candida Infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Cystitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal Skin Infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Genital Herpes Zoster			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral Candidiasis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral Fungal Infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Oral Herpes			
subjects affected / exposed	3 / 19 (15.79%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Paronychia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	4	3
Pharyngitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin Infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	6
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 19 (10.53%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	3	4	0
Urinary Tract Infection			
subjects affected / exposed	5 / 19 (26.32%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	8	0	0
Vulvitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Herpes Zoster			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	8 / 19 (42.11%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	8	1	3
Dehydration			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Diabetes Mellitus			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	5	0	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	3 / 19 (15.79%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	1
Hyperkalaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	4 / 19 (21.05%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	4
Hypocalcaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	1
Hypomagnesaemia			

subjects affected / exposed	3 / 19 (15.79%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Hyponatraemia			
subjects affected / exposed	2 / 19 (10.53%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 October 2011	Amendment 1 • Clarification of starting dose for PF-05212384. • LIC, additional examinations and PK for Japanese patients. • Clarification of eligibility criteria for Japanese patients. • Lead-in PK sub-study. • Addition of appendices relevant only to Japanese amendment. • Other administrative changes.
17 April 2012	Amendment 2 Clarification of starting dose for PF-05212384. • Addition of PK sub-study. • Addition of PD endpoint of cholesterol and triglyceride changes. • Updated safety text to match Company standards. • Improvement of hyperglycemia management guidelines, including editing of two eligibility criteria.
03 August 2012	Amendment 3 • Addition of additional PK blood draws in PK sub-study. • Addition of language which defines end of survival follow-up period. • Updated requirement for triglyceride and cholesterol testing (fasted state). • Addition of standard Pfizer CSP template language regarding pregnancy testing for eligibility purposes and lifestyle guidelines with regards to birth control, safety data ollection, temperature monitoring in drug storage area, and record retention. • Clarification of language regarding statistical analysis of ECG data. • Addition of language to clarify provision of study drug to patients in the event that the sponsor ended the study prematurely.
10 August 2012	Amendment 4 (Japan Specific) • Addition of patients in LIC. • Addition of PK blood draws in PK sub-study. • Addition of PD endpoint of cholesterol and triglyceride changes (fasted state). • Revision of hyperglycemia management guidelines, including editing of two eligibility criteria. • Updated dose modification schedule for PF-04691502 and PF-05212384 in LIC. • Updated safety text to match Company standards. • Addition of language defining end of survival follow-up period. • Addition of standard Pfizer CSP template language regarding pregnancy testing for eligibility purposes and lifestyle guidelines with regards to birth control, safety data collection, temperature monitoring in drug storage area, and record retention. • Clarification of language regarding statistical analysis of ECG data. • Updated guidelines for safety data reviewing. • Addition of language to clarify provision of study drug to patients in the event that the sponsor ended the study prematurely.
31 August 2012	Amendment 5 • Reduction of the starting dose for PF-04691502. • Reduction of the dose of PF-04691502 for ongoing patients. • Updated phase 1 clinical data for PF-04691502 and PF-05212384. • Addition of required CT scans of chest at baseline and every 8 weeks. • Allowed for 20 patients with starting dose of 6 mg of PF-04691502 in Stage 1 for each PF-04691502 arm. • Updated dose modification guidelines with respiratory toxicities. • Modified CSP-specific SAEs.

10 September 2012	Amendment 6 (Japan Specific) • Reduction of the dose of PF-04691502 for ongoing patients of the main study. • Addition of 2 mg cohort in LIC. • Updated guidelines for safety data reviewing. • Updated phase 1 clinical data for PF-04691502 and PF-05212384. • Addition of required CT scans of chest at baseline and every 8 weeks. • Allowed for 20 patients with starting dose of 6 mg of PF-04691502 in Stage 1 for each PF-04691502 arm. • Updated dose modification guidelines with respiratory toxicities. • Modified CSP-specific SAEs.
02 November 2012	• Amendment 7 • Enrollment to arms of the study which utilized PF-04691502 was discontinued. • Long term follow up portion of the study was removed for those patients on the PF-04691502 arms of the study. • Changed timing for pregnancy testing during screening. • Glucose testing changed to fasted or non-fasted for all study patients. • Post study SAE reporting requirements changed to specify that SAEs clearly related to subsequent anti-cancer treatments (including other clinical studies) or disease progression were not to be reported. • Patients on the PF-04691502 arms of the study no longer needed to perform blood draws for PK or optional tumor biopsies for PD. • There was no formal PK analysis for PF-04691502, only concentration-time listings. • Total number of patients enrolled to the study was changed as a result of stopping further enrollment to the PF-04691502 arms of the study. • Female patients of childbearing potential had to agree to use 2 methods of highly effective contraception. • Specific criteria for QTc analyses were removed, to be addressed in the SAP. • Removal of analysis of PF-04691502 concentration vs. QT.
09 November 2012	Amendment 8 (Japan Specific) (09 November 2012) • Enrollment to arms of the study which utilized PF-04691502 was discontinued. • Long term follow up portion of the study was removed for those patients on the PF-04691502 arms of the study. • Changed timing for pregnancy testing during screening. • Glucose testing changed to fasted OR non-fasted for all study patients. • Post study SAE reporting requirements changed to specify that SAEs clearly related to subsequent anti-cancer treatments (including other clinical studies) or disease progression were not to be reported. • Patients on the PF-04691502 arms of the study no longer needed to perform blood draws for PK or optional tumor biopsies for PD. • There was no formal PK analysis for PF-04691502, only concentration-time listings. • Total number of patients enrolled to the study had changed as a result of stopping further enrollment to the PF-04691502 arms of the study. • Female subjects of childbearing potential had to agree to use 2 methods of highly effective contraception. • Specific criteria for QTc analyses were removed, to be addressed in the statistical analysis plan. • Removal of analysis of PF-04691502 concentration vs QT.
19 February 2015	Amendment 9 (Japan specific) • Text was added to describe termination of the study and rationale for termination. • Reduction of tumor assessment schedule. • Addition of plasma sampling for circulating DNA analysis. • Procedure for blood draw for this DNA analysis was added. • Study endpoint and objectives were updated accordingly to support this DNA analysis.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
23 January 2014	Enrollment to B1271004 was discontinued on 23 January 2014 following a strategic decision based on initial results which were contrary to the hypothesis that a Stathmin high status (PI3K activated) would predict for better efficacy. The CSP indicated that the study would proceed into Stage 2 of the study if at least 8 clinical benefit responders were observed in 20 response evaluable patients at the end of Stage 1. As of 14 January 2014, 9 clinical benefit responders had been identified in the 'Stathmin low' arm of the study. Although this met the CSP defined criteria for advancement in to Stage 2 of the study, the sponsor determined not to proceed to Stage 2 based on the overall clinical findings. Patients who were already receiving treatment in Stage 1 of the study continued to take study drug. Patients were no longer followed up for OS and the planned OS analysis was not performed.	-

Notes:

Limitations and caveats

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

None

Notes: