Clinical trial results:
Cross-tumoral Phase 2 clinical trial exploring Crizotinib (PF-02341066) in patients with advanced tumours induced by causal alterations of either ALK or MET.

Summary

EudraCT number	2011-001988-52
Trial protocol	BE DE GB AT NL FR NO SI IT PL DK SK
Global end of trial date	30 October 2022

Results information

Result version number	v1 (current)
This version publication date	23 May 2024
First version publication date	23 May 2024

Trial information

Trial identification

Sponsor protocol code	90101

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01524926
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	EORTC
Sponsor organisation address	Avenue E Mounier 83/11, Brussels, Belgium, 1200
Public contact	Head of Regulatory Affairs, EORTC, 32 27741035, regulatory@eortc.be
Scientific contact	Head of Regulatory Affairs, EORTC, 32 27741035, regulatory@eortc.be

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	05 March 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 October 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The study will primarily assess the efficacy of crizotinib in a variety of tumors with alterations in ALK and/or MET pathways. The targeted patient population will include patients with tumors harboring specific
alterations leading to ALK and/or MET activation, where tyrosine kinase inhibitors against these targets have not yet been adequately explored.

Protection of trial subjects:

The responsible investigator will ensure that this study is conducted in agreement with either the Declaration of Helsinki (available on the World Medical Association web site (http://www.wma.net)) and/or the laws and regulations of the country, whichever provides the greatest protection of the patient.
The protocol has been written, and the study will be conducted according to the ICH Harmonized Tripartite Guideline on Good Clinical Practice (ICH-GCP, available online at https://www.ema.europa.eu/documents/scientific-guideline/ich-e6-r1-guideline-good-clinicalpractice_en.pdf).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 36
Country: Number of subjects enrolled	Belgium: 13
Country: Number of subjects enrolled	France: 28
Country: Number of subjects enrolled	Germany: 45
Country: Number of subjects enrolled	Italy: 20
Country: Number of subjects enrolled	Netherlands: 11
Country: Number of subjects enrolled	Norway: 7
Country: Number of subjects enrolled	Poland: 22
Country: Number of subjects enrolled	Slovakia: 13
Country: Number of subjects enrolled	Slovenia: 3
Worldwide total number of subjects	198
EEA total number of subjects	162

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)	7
Adults (18-64 years)	170
From 65 to 84 years	21
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patient recruitment followed a three steps procedure: - step 1: registration - step 2: central histopathology confirmation - step 3: enrollment.
Subjects must meet all of the eligibility criteria to be eligible for treatment with crizotinib. Total time between step 1 and step 3, allowing treatment, should not exceed 7
weeks.

Pre-assignment

Screening details:

It includes documentation of extent of disease, ophtalmologic examination, ECG, LVEF (echo or MUGA scan), laboratory examinations, documentation of adverse events and concomitant medications. If applicable, a pregnancy.

Pre-assignment period milestones

Number of subjects started	198
Number of subjects completed	141

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Screening failures: 56
Reason: Number of subjects	Consent withdrawn by subject: 1

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Anaplastic large cell lymphoma (ALCL)

Arm description:

ALCL is a rare variant of Non-Hodgkin’s lymphoma associated with ALK alterations in 80-90% of cases diagnosed in adolescents and young adults

Arm type	Cohort
Investigational medicinal product name	Crizotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Oral solution
Routes of administration	Oral use

Dosage and administration details:

Patients of 15 years old or older
Crizotinib will be administered orally at a dose of 250 mg twice daily (BID) at approximately the same time each day on a continuous daily dosing schedule, i.e. no break in dosing, in the absence of drug related toxicity.

Patients younger than 15 years old
Crizotinib will be administered orally at a dose of 280 mg/m²/dose BID at approximately the same time each day on a continuous daily dosing schedule, i.e. no break in dosing, in the absence of drug related toxicity.

The use of capsules is recommended if the calculated dose with +/-10% can be given by the existing capsules, otherwise it is recommended to use oral solution.
Patients unable to swallow should receive the oral solution.

Investigational medicinal product name	Crizotinib
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Other name	
Pharmaceutical forms	Capsule, Oral solution
Routes of administration	Oral use

Dosage and administration details:

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Patients unable to swallow should receive the oral solution.

Arm title	Inflammatory myofibroblastic tumor (IMFT)

Arm description:

IMFT is a distinctive mesenchymal neoplasm characterized by a spindle-cell proliferation with an inflammatory infiltrate. These tumors occur primarily during the first two decades of life and typically arise in the lung, retroperitoneum, or abdominopelvic region. Abdominal tumors may be multifocal. Lesional cells are predominantly myofibroblasts in a myxoid to collagenous stroma admixed with inflammatory cells. Local recurrence may occur after initial surgery, with a low risk of distant metastases, so that IMFTs are considered to be soft tissue tumors of intermediate biologic potential, with only a small
fraction behaving aggressively.

Arm type	Cohort
Investigational medicinal product name	Crizotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Oral solution
Routes of administration	Oral use

Dosage and administration details:

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Patients unable to swallow should receive the oral solution.

Arm title	Papillary renal cell carcinoma type 1 (PRCC)

Arm description:

PRCC occurs in sporadic and hereditary forms, accounting for 10 to 15% of carcinomas of the renal tubular epithelium. Current classification of a renal tumor as PRCC requires a minimum of 75% papillary or tubulopapillary architecture. Delahunt and Eble proposed a subclassification of PRCCs into type 1 and type 2 tumors, based on histological features.

Arm type	Cohort

Investigational medicinal product name	Crizotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Oral solution
Routes of administration	Oral use

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The use of capsules is recommended if the calculated dose with +/-10% can be given by the existing capsules, otherwise it is recommended to use oral solution.
Patients unable to swallow should receive the oral solution.

Arm title	Alveolar soft part sarcoma (ASPS)

Arm description:

ASPS is a clinically and morphologically distinct soft tissue sarcoma first defined and named by Christopherson et al. in 1952. It is an uncommon tumor and uniformly malignant. Its frequency is estimated at 0.5 to 1% of all soft tissue sarcomas and it occurs principally in adolescents and young adults. There are two main locations of the tumor. When it occurs in adults, it is predominantly in the lower extremities, although it has been described in a variety of unusual locations, including the female genital tract, mediastinum, breast, urinary bladder, gastrointestinal tract, and bone. When the tumor affects infants and children, it is often located in the head and neck region, especially the orbit and tongue. ASPS usually presents as a slowly growing, painless mass.

Arm type	Cohort
Investigational medicinal product name	Crizotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Oral solution
Routes of administration	Oral use

Dosage and administration details:

Patients of 15 years old or older
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The use of capsules is recommended if the calculated dose with +/-10% can be given by the existing capsules, otherwise it is recommended to use oral solution.
Patients unable to swallow should receive the oral solution.

Arm title	Clear cell sarcoma (CCSA)

Arm description:

CCSA is an aggressive soft tissue sarcoma that typically develops in the tendons and aponeuroses of children and young adults. A high rate of local and distant recurrence results in a 5 year overall survival of
only 50%. Five year survival decreases to 20% for metastatic disease, consistent with the tumor’s profound resistance to conventional chemotherapy and radiation therapy.

Arm type	Cohort

Investigational medicinal product name	Crizotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Oral solution
Routes of administration	Oral use

Dosage and administration details:

Patients of 15 years old or older
Crizotinib will be administered orally at a dose of 250 mg twice daily (BID) at approximately the same time each day on a continuous daily dosing schedule, i.e. no break in dosing, in the absence of drug related toxicity.

Patients younger than 15 years old
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The use of capsules is recommended if the calculated dose with +/-10% can be given by the existing capsules, otherwise it is recommended to use oral solution.
Patients unable to swallow should receive the oral solution.

Arm title	Alveolar rhabdomyosarcoma (ARMS)

Arm description:

Rhabdomyosarcoma is the most common soft tissue sarcoma in childhood and does also occur in adults. Although the precise cell type from which the tumor originates is still a matter of debate, the evidence points towards the myogenic lineage. Rhabdomyosarcoma expresses a variety of markers typical of both embryonic and mature skeletal muscle. A widely employed histologic classification of rhabdomyosarcomas defines three subtypes, differing from each other for body location, occurrence, mean patient age, and prognosis. The alveolar subtype (ARMS) typically consists of small round densely packed cells, resembling pulmonary alveoli, and it occurs more often in the trunk and extremities. Expression profiling of different subtypes of rhabdomyosarcomas has revealed that their two signatures differ widely.

Arm type	Cohort
Investigational medicinal product name	Crizotinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Oral solution
Routes of administration	Oral use

Dosage and administration details:

Patients of 15 years old or older
Crizotinib will be administered orally at a dose of 250 mg twice daily (BID) at approximately the same time each day on a continuous daily dosing schedule, i.e. no break in dosing, in the absence of drug related toxicity.

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The use of capsules is recommended if the calculated dose with +/-10% can be given by the existing capsules, otherwise it is recommended to use oral solution.
Patients unable to swallow should receive the oral solution.

Number of subjects in period 1[1]	Anaplastic large cell lymphoma (ALCL)	Inflammatory myofibroblastic tumor (IMFT)	Papillary renal cell carcinoma type 1 (PRCC)
Started	3	20	23
Completed	3	20	23

Number of subjects in period 1[1]	Alveolar soft part sarcoma (ASPS)	Clear cell sarcoma (CCSA)	Alveolar rhabdomyosarcoma (ARMS)
Started	48	34	13
Completed	48	34	13

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Only the 141 patients completing the pre-assignment period entered in this study period.

Baseline characteristics

Reporting groups	
Reporting group title	Anaplastic large cell lymphoma (ALCL)

Reporting group description:

ALCL is a rare variant of Non-Hodgkin's lymphoma associated with ALK alterations in 80-90% of cases diagnosed in adolescents and young adults

Reporting group title	Inflammatory myofibroblastic tumor (IMFT)

Reporting group description:

IMFT is a distinctive mesenchymal neoplasm characterized by a spindle-cell proliferation with an inflammatory infiltrate. These tumors occur primarily during the first two decades of life and typically arise in the lung, retroperitoneum, or abdominopelvic region. Abdominal tumors may be multifocal. Lesional cells are predominantly myofibroblasts in a myxoid to collagenous stroma admixed with inflammatory cells. Local recurrence may occur after initial surgery, with a low risk of distant metastases, so that IMFTs are considered to be soft tissue tumors of intermediate biologic potential, with only a small
fraction behaving aggressively.

Reporting group title	Papillary renal cell carcinoma type 1 (PRCC)

Reporting group description:

PRCC occurs in sporadic and hereditary forms, accounting for 10 to 15% of carcinomas of the renal tubular epithelium. Current classification of a renal tumor as PRCC requires a minimum of 75% papillary or tubulopapillary architecture. Delahunt and Eble proposed a subclassification of PRCCs into type 1 and type 2 tumors, based on histological features.

Reporting group title	Alveolar soft part sarcoma (ASPS)

Reporting group description:

ASPS is a clinically and morphologically distinct soft tissue sarcoma first defined and named by Christopherson et al. in 1952. It is an uncommon tumor and uniformly malignant. Its frequency is estimated at 0.5 to 1% of all soft tissue sarcomas and it occurs principally in adolescents and young adults. There are two main locations of the tumor. When it occurs in adults, it is predominantly in the lower extremities, although it has been described in a variety of unusual locations, including the female genital tract, mediastinum, breast, urinary bladder, gastrointestinal tract, and bone. When the tumor affects infants and children, it is often located in the head and neck region, especially the orbit and tongue. ASPS usually presents as a slowly growing, painless mass.

Reporting group title	Clear cell sarcoma (CCSA)

Reporting group description:

CCSA is an aggressive soft tissue sarcoma that typically develops in the tendons and aponeuroses of children and young adults. A high rate of local and distant recurrence results in a 5 year overall survival of
only 50%. Five year survival decreases to 20% for metastatic disease, consistent with the tumor's profound resistance to conventional chemotherapy and radiation therapy.

Reporting group title	Alveolar rhabdomyosarcoma (ARMS)

Reporting group description:

Rhabdomyosarcoma is the most common soft tissue sarcoma in childhood and does also occur in adults. Although the precise cell type from which the tumor originates is still a matter of debate, the evidence points towards the myogenic lineage. Rhabdomyosarcoma expresses a variety of markers typical of both embryonic and mature skeletal muscle. A widely employed histologic classification of rhabdomyosarcomas defines three subtypes, differing from each other for body location, occurrence, mean patient age, and prognosis. The alveolar subtype (ARMS) typically consists of small round densely packed cells, resembling pulmonary alveoli, and it occurs more often in the trunk and extremities. Expression profiling of different subtypes of rhabdomyosarcomas has revealed that their two signatures differ widely.

Reporting group values	Anaplastic large cell lymphoma (ALCL)	Inflammatory myofibroblastic tumor (IMFT)	Papillary renal cell carcinoma type 1 (PRCC)
Number of subjects	3	20	23

Age categorical			
Age group			
Units: Subjects			
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	1	1	0
Adults (18-64 years)	2	15	14
From 65-84 years	0	4	9
85 years and over	0	0	0
Age continuous			
Age (years)			
Units: years			
median	21	45	61
full range (min-max)	15 to 24	15 to 78	49 to 81
Gender categorical			
Gender			
Units: Subjects			
Female	0	9	3
Male	3	11	20
ECOG			
Eastern Cooperative Oncology Group (ECOG) performance status / Lansky play scale			
Units: Subjects			
Value 0	2	11	13
Value 1	1	8	10
Value 2	0	1	0
Previous surgery			
Any previous major surgery			
Units: Subjects			
No	3	10	0
Yes	0	10	23
Prior systemic anticancer therapy			
Any prior systemic anticancer therapy			
Units: Subjects			
No	0	12	14
Yes	3	8	9
Chemotherapy			
Chemotherapy			
Units: Subjects			
No	0	13	22
Yes	3	7	1
Any palliative radiotherapy			
Any palliative radiotherapy			
Units: Subjects			
No	3	18	23
Yes	0	2	0
Radiotherapy			
Radiotherapy			
Units: Subjects			
No	3	17	23
Yes	0	3	0

Immunotherapy			
Immunotherapy			
Units: Subjects			
No	1	20	22
Yes	2	0	1
Other anticancer therapy			
Other anticancer therapy			
Units: Subjects			
No	2	17	14
Yes	1	3	9

Reporting group values	Alveolar soft part sarcoma (ASPS)	Clear cell sarcoma (CCSA)	Alveolar rhabdomyosarcoma (ARMS)
Number of subjects	48	34	13
Age categorical			
Age group			
Units: Subjects			
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	1	0	2
Adults (18-64 years)	46	34	11
From 65-84 years	1	0	0
85 years and over	0	0	0
Age continuous			
Age (years)			
Units: years			
median	30.5	44	30
full range (min-max)	16 to 69	18 to 64	16 to 48
Gender categorical			
Gender			
Units: Subjects			
Female	22	13	2
Male	26	21	11
ECOG			
Eastern Cooperative Oncology Group (ECOG) performance status / Lansky play scale			
Units: Subjects			
Value 0	36	17	2
Value 1	11	12	5
Value 2	1	5	6
Previous surgery			
Any previous major surgery			
Units: Subjects			
No	17	2	8
Yes	31	32	5
Prior systemic anticancer therapy			
Any prior systemic anticancer therapy			
Units: Subjects			
No	25	25	0
Yes	23	9	13
Chemotherapy			

Chemotherapy			
Units: Subjects			
No	37	25	0
Yes	11	9	13
Any palliative radiotherapy			
Any palliative radiotherapy			
Units: Subjects			
No	31	22	4
Yes	17	12	9
Radiotherapy			
Radiotherapy			
Units: Subjects			
No	23	17	1
Yes	25	17	12
Immunotherapy			
Immunotherapy			
Units: Subjects			
No	48	33	13
Yes	0	1	0
Other anticancer therapy			
Other anticancer therapy			
Units: Subjects			
No	32	33	12
Yes	16	1	1

Reporting group values	Total		
Number of subjects	141		
Age categorical			
Age group			
Units: Subjects			
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	5		
Adults (18-64 years)	122		
From 65-84 years	14		
85 years and over	0		
Age continuous			
Age (years)			
Units: years			
median			
full range (min-max)	-		
Gender categorical			
Gender			
Units: Subjects			
Female	49		
Male	92		
ECOG			
Eastern Cooperative Oncology Group (ECOG) performance status / Lansky play scale			
Units: Subjects			
Value 0	81		

Value 1	47		
Value 2	13		
Previous surgery			
Any previous major surgery			
Units: Subjects			
No	40		
Yes	101		
Prior systemic anticancer therapy			
Any prior systemic anticancer therapy			
Units: Subjects			
No	76		
Yes	65		
Chemotherapy			
Chemotherapy			
Units: Subjects			
No	97		
Yes	44		
Any palliative radiotherapy			
Any palliative radiotherapy			
Units: Subjects			
No	101		
Yes	40		
Radiotherapy			
Radiotherapy			
Units: Subjects			
No	84		
Yes	57		
Immunotherapy			
Immunotherapy			
Units: Subjects			
No	137		
Yes	4		
Other anticancer therapy			
Other anticancer therapy			
Units: Subjects			
No	110		
Yes	31		

Subject analysis sets

Subject analysis set title	Safety population
Subject analysis set type	Safety analysis
Subject analysis set description: All patients who started the treatment	
Subject analysis set title	Per-Protocol Population
Subject analysis set type	Per protocol
Subject analysis set description: all eligible and evaluable patients	
Subject analysis set title	PRCC Cohort
Subject analysis set type	Per protocol

Subject analysis set description:
PRCC Cohort

Subject analysis set title	CCSA Cohort
Subject analysis set type	Per protocol

Subject analysis set description:
CCSA Cohort

Subject analysis set title	ARMS cohort
Subject analysis set type	Per protocol

Subject analysis set description:
ARMS Cohort

Subject analysis set title	ASPS Cohort
Subject analysis set type	Per protocol

Subject analysis set description:
ASPS Cohort

Subject analysis set title	IMFT Cohort
Subject analysis set type	Per protocol

Subject analysis set description:
IMFT Cohort

Reporting group values	Safety population	Per-Protocol Population	PRCC Cohort
Number of subjects	141	123	23
Age categorical			
Age group			
Units: Subjects			
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	5		
Adults (18-64 years)	122		
From 65-84 years	14		
85 years and over	0		
Age continuous			
Age (years)			
Units: years			
median	39	39.5	
full range (min-max)	15 to 81	15 to 81	
Gender categorical			
Gender			
Units: Subjects			
Female	49	44	
Male	92	82	
ECOG			
Eastern Cooperative Oncology Group (ECOG) performance status / Lansky play scale			
Units: Subjects			
Value 0	81	77	
Value 1	47	43	
Value 2	13	6	
Previous surgery			
Any previous major surgery			
Units: Subjects			
No	29		

Yes	112		
Prior systemic anticancer therapy			
Any prior systemic anticancer therapy			
Units: Subjects			
No	76		
Yes	62		
Chemotherapy			
Chemotherapy			
Units: Subjects			
No	97		
Yes	44		
Any palliative radiotherapy			
Any palliative radiotherapy			
Units: Subjects			
No		101	
Yes		40	
Radiotherapy			
Radiotherapy			
Units: Subjects			
No		84	
Yes		57	
Immunotherapy			
Immunotherapy			
Units: Subjects			
No		137	
Yes		4	
Other anticancer therapy			
Other anticancer therapy			
Units: Subjects			
No		110	
Yes		31	

Reporting group values	CCSA Cohort	ARMS cohort	ASPS Cohort
Number of subjects	28	8	45
Age categorical			
Age group			
Units: Subjects			
Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
Age (years)			
Units: years median full range (min-max)			

Gender categorical			
Gender			
Units: Subjects			
Female Male			
ECOG			
Eastern Cooperative Oncology Group (ECOG) performance status / Lansky play scale			
Units: Subjects			
Value 0 Value 1 Value 2			
Previous surgery			
Any previous major surgery			
Units: Subjects			
No Yes			
Prior systemic anticancer therapy			
Any prior systemic anticancer therapy			
Units: Subjects			
No Yes			
Chemotherapy			
Chemotherapy			
Units: Subjects			
No Yes			
Any palliative radiotherapy			
Any palliative radiotherapy			
Units: Subjects			
No Yes			
Radiotherapy			
Radiotherapy			
Units: Subjects			
No Yes			
Immunotherapy			
Immunotherapy			
Units: Subjects			
No Yes			
Other anticancer therapy			
Other anticancer therapy			
Units: Subjects			
No Yes			

Reporting group values	IMFT Cohort		
Number of subjects	19		

Age categorical			
Age group			
Units: Subjects			
Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
Age (years)			
Units: years median full range (min-max)			
Gender categorical			
Gender			
Units: Subjects			
Female Male			
ECOG			
Eastern Cooperative Oncology Group (ECOG) performance status / Lansky play scale			
Units: Subjects			
Value 0 Value 1 Value 2			
Previous surgery			
Any previous major surgery			
Units: Subjects			
No Yes			
Prior systemic anticancer therapy			
Any prior systemic anticancer therapy			
Units: Subjects			
No Yes			
Chemotherapy			
Chemotherapy			
Units: Subjects			
No Yes			
Any palliative radiotherapy			
Any palliative radiotherapy			
Units: Subjects			
No Yes			
Radiotherapy			
Radiotherapy			
Units: Subjects			
No Yes			

Immunotherapy			
Immunotherapy			
Units: Subjects			
No Yes			
Other anticancer therapy			
Other anticancer therapy			
Units: Subjects			
No Yes			

End points reporting groups

Reporting group title	Anaplastic large cell lymphoma (ALCL)

Reporting group description:

ALCL is a rare variant of Non-Hodgkin’s lymphoma associated with ALK alterations in 80-90% of cases diagnosed in adolescents and young adults

Reporting group title	Inflammatory myofibroblastic tumor (IMFT)

Reporting group description:

IMFT is a distinctive mesenchymal neoplasm characterized by a spindle-cell proliferation with an inflammatory infiltrate. These tumors occur primarily during the first two decades of life and typically arise in the lung, retroperitoneum, or abdominopelvic region. Abdominal tumors may be multifocal. Lesional cells are predominantly myofibroblasts in a myxoid to collagenous stroma admixed with inflammatory cells. Local recurrence may occur after initial surgery, with a low risk of distant metastases, so that IMFTs are considered to be soft tissue tumors of intermediate biologic potential, with only a small
fraction behaving aggressively.

Reporting group title	Papillary renal cell carcinoma type 1 (PRCC)

Reporting group description:

PRCC occurs in sporadic and hereditary forms, accounting for 10 to 15% of carcinomas of the renal tubular epithelium. Current classification of a renal tumor as PRCC requires a minimum of 75% papillary or tubulopapillary architecture. Delahunt and Eble proposed a subclassification of PRCCs into type 1 and type 2 tumors, based on histological features.

Reporting group title	Alveolar soft part sarcoma (ASPS)

Reporting group description:

ASPS is a clinically and morphologically distinct soft tissue sarcoma first defined and named by Christopherson et al. in 1952. It is an uncommon tumor and uniformly malignant. Its frequency is estimated at 0.5 to 1% of all soft tissue sarcomas and it occurs principally in adolescents and young adults. There are two main locations of the tumor. When it occurs in adults, it is predominantly in the lower extremities, although it has been described in a variety of unusual locations, including the female genital tract, mediastinum, breast, urinary bladder, gastrointestinal tract, and bone. When the tumor affects infants and children, it is often located in the head and neck region, especially the orbit and tongue. ASPS usually presents as a slowly growing, painless mass.

Reporting group title	Clear cell sarcoma (CCSA)

Reporting group description:

CCSA is an aggressive soft tissue sarcoma that typically develops in the tendons and aponeuroses of children and young adults. A high rate of local and distant recurrence results in a 5 year overall survival of
only 50%. Five year survival decreases to 20% for metastatic disease, consistent with the tumor’s profound resistance to conventional chemotherapy and radiation therapy.

Reporting group title	Alveolar rhabdomyosarcoma (ARMS)

Reporting group description:

Rhabdomyosarcoma is the most common soft tissue sarcoma in childhood and does also occur in adults. Although the precise cell type from which the tumor originates is still a matter of debate, the evidence points towards the myogenic lineage. Rhabdomyosarcoma expresses a variety of markers typical of both embryonic and mature skeletal muscle. A widely employed histologic classification of rhabdomyosarcomas defines three subtypes, differing from each other for body location, occurrence, mean patient age, and prognosis. The alveolar subtype (ARMS) typically consists of small round densely packed cells, resembling pulmonary alveoli, and it occurs more often in the trunk and extremities. Expression profiling of different subtypes of rhabdomyosarcomas has revealed that their two signatures differ widely.

Subject analysis set title	Safety population
Subject analysis set type	Safety analysis

Subject analysis set description:

All patients who started the treatment

Subject analysis set title	Per-Protocol Population
Subject analysis set type	Per protocol

Subject analysis set description:

all eligible and evaluable patients

Subject analysis set title	PRCC Cohort
Subject analysis set type	Per protocol
Subject analysis set description: PRCC Cohort	
Subject analysis set title	CCSA Cohort
Subject analysis set type	Per protocol
Subject analysis set description: CCSA Cohort	
Subject analysis set title	ARMS cohort
Subject analysis set type	Per protocol
Subject analysis set description: ARMS Cohort	
Subject analysis set title	ASPS Cohort
Subject analysis set type	Per protocol
Subject analysis set description: ASPS Cohort	
Subject analysis set title	IMFT Cohort
Subject analysis set type	Per protocol
Subject analysis set description: IMFT Cohort	

Primary: Overall Response Rate

End point title	Overall Response Rate
End point description: The primary endpoint overall response is defined as confirmed complete and partial response (RECIST 1.1) observed during the whole treatment period	
End point type	Primary
End point timeframe: The whole treatment period	

End point values	Anaplastic large cell lymphoma (ALCL)	Inflammatory myofibroblastic tumor (IMFT)	Papillary renal cell carcinoma type 1 (PRCC)	Alveolar soft part sarcoma (ASPS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[1]	19	23	45
Units: Subjects				
Reponders		9	4	2
Non-responders		10	19	43

Notes:

[1] - Too small sample size for analysis

End point values	Clear cell sarcoma (CCSA)	Alveolar rhabdomyosarcoma (ARMS)	PRCC Cohort	CCSA Cohort
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	28	8	23	28
Units: Subjects				
Reponders	1	1	4	1
Non-responders	27	7	19	27

End point values	ARMS cohort	ASPS Cohort	IMFT Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	8	45	19	
Units: Subjects				
Reponders	1	2	1	
Non-responders	7	43	27	

Statistical analyses

Statistical analysis title	Primary decision rule - PRCC

Statistical analysis description:

a Simon's optimal two stage design (alpha=beta=0.10) was implemented. The first stage will require 12 eligible and evaluable* patients in each sub-cohort. If at least 2 patients respond, the sub-cohort goes to the second stage and the accrual is continued until 35 eligible and evaluable* patients. At that time, if less than 6 patients respond, the sub-cohort is stopped and will be declared as ineffective. If at least 6 of the 35 patients respond (17%), the sub-cohort will be deemed successfull.

Comparison groups	Papillary renal cell carcinoma type 1 (PRCC) v PRCC Cohort
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0 [3]
Method	Not Applicable, system blocks otherwise
Parameter estimate	Proportion
Point estimate	0.174
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.049
upper limit	0.388

Notes:

[2] - The analysis is done by implementing the decision rule.
This is a single arm test - two arms were provided due to EUDRACT reporting system limitation. The primary test is performed in the final decision rule population only.
[3] - The study did not reach the number of patients needed.
The confidence interval of the response rate includes 10% so the arm was not deemed successful.

Statistical analysis title	Primary decision rule - CCSA

Statistical analysis description:

a Simon's optimal two stage design (alpha=beta=0.10) was implemented. The first stage will require 12 eligible and evaluable patients in each sub-cohort. If at least 2 patients respond, the sub-cohort goes to the second stage and the accrual is continued until 35 eligible and evaluable patients. At that time, if less than 6 patients respond, the sub-cohort is stopped and will be declared as ineffective. If at least 6 of the 35 patients respond (17%), the sub-cohort will be deemed successfull.

Comparison groups	Clear cell sarcoma (CCSA) v CCSA Cohort

Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	= 0 [5]
Method	Not Applicable, system blocks otherwise
Parameter estimate	Proportion
Point estimate	0.036
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.001
upper limit	0.183
Variability estimate	Standard deviation
Dispersion value	0

Notes:

[4] - The analysis is done by implementing the decision rule.
This is a single arm test - two arms were provided due to EUDRACT reporting system limitation. The primary test is performed in the final decision rule population only.
[5] - The study did not reach the number of patients needed.
The confidence interval of the response rate includes 10% so the arm was not deemed successful.

Statistical analysis title	Primary decision rule - ARMS

Statistical analysis description:

a Simon's optimal two stage design (alpha=beta=0.10) was implemented. The first stage will require 12 eligible and evaluable patients in each sub-cohort. If at least 2 patients respond, the sub-cohort goes to the second stage and the accrual is continued until 35 eligible and evaluable patients. At that time, if less than 6 patients respond, the sub-cohort is stopped and will be declared as ineffective. If at least 6 of the 35 patients respond (17%), the sub-cohort will be deemed successfull.

Comparison groups	Alveolar rhabdomyosarcoma (ARMS) v ARMS cohort
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0 [7]
Method	Not Applicable, system blocks otherwise
Parameter estimate	Proportion
Point estimate	0.125
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.003
upper limit	0.526

Notes:

[6] - The analysis is done by implementing the decision rule.
This is a single arm test - two arms were provided due to EUDRACT reporting system limitation. The primary test is performed in the final decision rule population only.
[7] - The study did not reach the number of patients needed.
The confidence interval of the response rate includes 10% so the arm was not deemed successful.

Statistical analysis title	Primary decision rule - ASPS

Statistical analysis description:

a Simon's optimal two stage design (alpha=beta=0.10) was implemented. The first stage will require 12 eligible and evaluable patients in each sub-cohort. If at least 2 patients respond, the sub-cohort goes to the second stage and the accrual is continued until 35 eligible and evaluable patients. At that time, if less than 6 patients respond, the sub-cohort is stopped and will be declared as ineffective. If at least 6 of the 35 patients respond (17%), the sub-cohort will be deemed successfull.

Comparison groups	Alveolar soft part sarcoma (ASPS) v ASPS Cohort

Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0 [9]
Method	Not Applicable, system blocks otherwise
Parameter estimate	Proportion
Point estimate	0.044
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.152

Notes:

[8] - The analysis is done by implementing the decision rule.
This is a single arm test - two arms were provided due to EUDRACT reporting system limitation. The primary test is performed in the final decision rule population only.
[9] - The confidence interval of the response rate includes 10% so the arm was not deemed successful.

Statistical analysis title	Primary decision rule - IMFT

Statistical analysis description:

a Simon's optimal two stage design (alpha=beta=0.10) was implemented. The first stage will require 12 eligible and evaluable patients in each sub-cohort. If at least 2 patients respond, the sub-cohort goes to the second stage and the accrual is continued until 35 eligible and evaluable patients. At that time, if less than 6 patients respond, the sub-cohort is stopped and will be declared as ineffective. If at least 6 of the 35 patients respond (17%), the sub-cohort will be deemed successfull.

Comparison groups	Inflammatory myofibroblastic tumor (IMFT) v IMFT Cohort
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	= 0 [11]
Method	Not Applicable, system blocks otherwise
Parameter estimate	Proportion
Point estimate	0.474
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.245
upper limit	0.711

Notes:

[10] - The analysis is done by implementing the decision rule.
This is a single arm test - two arms were provided due to EUDRACT reporting system limitation. The primary test is performed in the final decision rule population only.
[11] - The study did not reach the number of patients needed.
However, the confidence interval of the response rate includes 10% so the arm was deemed successful.

Secondary: Overal survival

End point title	Overal survival

End point description:

End point type	Secondary

End point timeframe:

Overall Survival (OS) is calculated as the time from enrollment to the date of death (any cause). Patients alive at the time of analysis will be censored at the last time they are known to be alive.

End point values	Anaplastic large cell lymphoma (ALCL)	Inflammatory myofibroblastic tumor (IMFT)	Papillary renal cell carcinoma type 1 (PRCC)	Alveolar soft part sarcoma (ASPS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[12]	19	23	45
Units: Months				
median (confidence interval 95%)	(to)	46.9 (20.2 to 100.0)	30.5 (12.4 to 74.5)	60.3 (38.1 to 74.6)

Notes:

[12] - Not analyzed due to small sample size

End point values	Clear cell sarcoma (CCSA)	Alveolar rhabdomyosarcoma (ARMS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	8		
Units: Months				
median (confidence interval 95%)	9.4 (7.6 to 14.5)	5.1 (.7 to 7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression free survival

End point title	Progression free survival

End point description:

End point type	Secondary

End point timeframe:

Progression free survival (PFS) will be the time interval between the date of enrollment and the date of disease progression or death (events), whichever comes first. If neither event has been observed, then the patient is censored

End point values	Anaplastic large cell lymphoma (ALCL)	Inflammatory myofibroblastic tumor (IMFT)	Papillary renal cell carcinoma type 1 (PRCC)	Alveolar soft part sarcoma (ASPS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[13]	19	23	45
Units: Months				
median (confidence interval 95%)	(to)	15.3 (5.6 to 52.6)	5.8 (2.6 to 28.7)	8.1 (4.2 to 11.6)

Notes:
[13] - Too small sample size for analysis

End point values	Clear cell sarcoma (CCSA)	Alveolar rhabdomyosarcoma (ARMS)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	8		
Units: Months				
median (confidence interval 95%)	4.2 (2.2 to 5.5)	1.2 (0.5 to 1.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected on a CRF to be submitted at pre-specified timepoint.

Adverse event reporting additional description:

CRF for AEs contains pre-specified items + additional boxes for all "other" AEs. (xx% AEs are reported as "other" and are not reported as not available from the list of SOC).
AEs are evaluated using CTC grading, SAEs using MedDra. Non-SAEs has not been collected specifically, all AEs will be reported in non-SAE section.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19

Reporting groups

Reporting group title	Anaplastic large cell lymphoma (ALCL)

Reporting group description:

Anaplastic large cell lymphoma (ALCL)

Reporting group title	Inflammatory myofibroblastic tumor (IMFT)

Reporting group description:

Inflammatory myofibroblastic tumor (IMFT)

Reporting group title	Alveolar rhabdomyosarcoma (ARMS)

Reporting group description:

Alveolar rhabdomyosarcoma (ARMS)

Reporting group title	Alveolar soft part sarcoma (ASPS)

Reporting group description:

Alveolar soft part sarcoma (ASPS)

Reporting group title	Clear cell sarcoma (CCSA)

Reporting group description:

Clear cell sarcoma (CCSA)

Reporting group title	Papillary renal cell carcinoma type 1 (PRCC)

Reporting group description:

Papillary renal cell carcinoma type 1 (PRCC)

Serious adverse events	Anaplastic large cell lymphoma (ALCL)	Inflammatory myofibroblastic tumor (IMFT)	Alveolar rhabdomyosarcoma (ARMS)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	6 / 20 (30.00%)	3 / 13 (23.08%)
number of deaths (all causes)	0	9	13
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FIBROMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
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			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
CHEST PAIN			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (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
CHILLS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
RESPIRATORY FAILURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
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			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERSTITIAL LUNG DISEASE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MEDIASTINAL HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
HALLUCINATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
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			
ALANINE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ELECTROCARDIOGRAM QT PROLONGED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (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
BLOOD CREATININE INCREASED			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (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
ASPARTATE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
REACTIVE GASTROPATHY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
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			
BRADYCARDIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
SYNCOPE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
AGRANULOCYTOSIS			

alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
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			
OESOPHAGEAL ULCER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
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			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
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			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (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
Infections and infestations			
SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (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
RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PHARYNGITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE OCCLUSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL ABSCESS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (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
SEPTIC SHOCK			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
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			
DEHYDRATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Alveolar soft part sarcoma (ASPS)	Clear cell sarcoma (CCSA)	Papillary renal cell carcinoma type 1 (PRCC)
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 48 (16.67%)	8 / 34 (23.53%)	4 / 23 (17.39%)
number of deaths (all causes)	22	31	11
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
FIBROMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
DEEP VEIN THROMBOSIS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (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			
CHEST PAIN			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHILLS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (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
FATIGUE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
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			
RESPIRATORY FAILURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
PNEUMONITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
INTERSTITIAL LUNG DISEASE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (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
MEDIASTINAL HAEMORRHAGE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Psychiatric disorders			
HALLUCINATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ELECTROCARDIOGRAM QT PROLONGED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPARTATE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
REACTIVE GASTROPATHY			

alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Cardiac disorders			
BRADYCARDIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (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
MYOCARDIAL INFARCTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
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			
SYNCOPE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
AGRANULOCYTOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (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
Gastrointestinal disorders			
OESOPHAGEAL ULCER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (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
DYSPHAGIA			

alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
NAUSEA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
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			
SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
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 TRACT INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
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			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PHARYNGITIS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (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
LOWER RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
DEVICE OCCLUSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
BRONCHITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (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
ABDOMINAL ABSCESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DEHYDRATION			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (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

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

Non-serious adverse events	Anaplastic large cell lymphoma (ALCL)	Inflammatory myofibroblastic tumor (IMFT)	Alveolar rhabdomyosarcoma (ARMS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	20 / 20 (100.00%)	13 / 13 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
NEO OTH PAIN AFTER PATHOLOGICAL FRACTURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
NEO OTH PATHOLOGICAL FRACTURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TUMOR PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	3 / 20 (15.00%)	2 / 13 (15.38%)
occurrences (all)	0	9	5
Vascular disorders			
HEMATOMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
HOT FLASHES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	2 / 3 (66.67%)	4 / 20 (20.00%)	1 / 13 (7.69%)
occurrences (all)	4	48	1
HYPOTENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LYMPHEDEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VAS OTH THORACIC OUTLET			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VAS OTH LEG VENOUS INSUFFICIENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VAS OTH PETECHIAE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
VAS OTH PULMONARY EMBOLI			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
THROMBOEMBOLIC EVENT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
SUR OTH POSTOPERATIVE PAIN			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
CHILLS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EDEMA FACE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	0	3	3
EDEMA LIMBS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	12 / 20 (60.00%)	2 / 13 (15.38%)
occurrences (all)	0	35	3
FATIGUE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	12 / 20 (60.00%)	7 / 13 (53.85%)
occurrences (all)	1	155	16
FEVER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	2 / 13 (15.38%)
occurrences (all)	0	3	3
GEN OTH NIGHT SWEATS (INTERMITTENT)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
GEN OTH ANASARCA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
GEN OTH DETERIORATION OF GENERAL CONDITION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GEN OTH INFLAMMATORY SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
GEN OTH NIGHT SWEAT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GEN OTH NIGHT SWEATS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	6	0
FLU LIKE SYMPTOMS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
GEN OTH PAINFUL SWELLING ABOVE RIGHT CLAVICLE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GEN OTH SWEAT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
GEN OTH WORSENING OF GENERAL CONDITION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	2	2	2
MALAISE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
NON-CARDIAC CHEST PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	0	3	4
PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	5 / 20 (25.00%)	2 / 13 (15.38%)
occurrences (all)	0	13	3
Immune system disorders			
ALLERGIC REACTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
IMM OTH ALLERGY OF FARINE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
BREAST PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
ERECTILE DYSFUNCTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GYNECOMASTIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
IRREGULAR MENSTRUATION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VAGINAL DISCHARGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
VAGINAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	4 / 20 (20.00%)	1 / 13 (7.69%)
occurrences (all)	3	16	1
DYSPNEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	5 / 20 (25.00%)	5 / 13 (38.46%)
occurrences (all)	0	13	5
EPISTAXIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
HOARSENESS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MEDIASTINAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ALLERGIC RHINITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PHARYNGOLARYNGEAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 3 (66.67%)	2 / 20 (10.00%)	2 / 13 (15.38%)
occurrences (all)	2	2	2
RES OTH PULMONARY DISCOMFORT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
PNEUMOTHORAX			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RES OTH BRONCHITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

RES OTH BRONCHORRHEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RES OTH CRIZOTINIB INDUCED INTERSTITIAL LUNG DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RES OTH DECREASED BREATH SOUNDS IN A STRAIGHT BASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
RES OTH DECREASED BREATH SOUNDS IN RIGHT BASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
RES OTH HEMOPTYSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RES OTH HEMOPTYSIS (PERIODIC)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RES OTH INTERSTITIAL LUNG DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RES OTH PHARYNGODYNIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RES OTH PNEUMONIA			

alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
PLEURITIC PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RES OTH TACHYPNEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
RES OTH TONSILLITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY FAILURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SORE THROAT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
VOICE ALTERATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
INSOMNIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	1 / 13 (7.69%)
occurrences (all)	0	2	3
ANXIETY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	3 / 20 (15.00%)	0 / 13 (0.00%)
occurrences (all)	0	17	0
DEPRESSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
PSY OTH MOOD SWINGS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
PSY OTH SADNESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
PSY OTH SLEEP DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
BLOOD PROLACTIN ABNORMAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CHOLESTEROL HIGH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SERUM AMYLASE INCREASED			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT CORRECTED INTERVAL PROLONGED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
GGT INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	7	0
INV OTH AGRANULOCYTOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INV OTH CRP INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
LIPASE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CREATININE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
WEIGHT LOSS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
WEIGHT GAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	6 / 20 (30.00%)	0 / 13 (0.00%)
occurrences (all)	0	35	0

WEIGHT LOSS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	6 / 20 (30.00%)	2 / 13 (15.38%)
occurrences (all)	12	15	4
Injury, poisoning and procedural complications			
BURN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
FALL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FRACTURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INJ OTH BLOCKED CATHETER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INJ OTH TICK BITE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
CAR OTH BRADYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CAR OTH CARDIAC SLOWING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CAR OTH DECREASED HEART RATE			

alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CAR OTH TACHYSYSTOLIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CAR OTH HEART MURMUR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CAR OTH MITRAL MURMUR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
CAR OTH SLOW-R-PROGRESSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CAR OTH TACHYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
CAR OTH DIASTOLIC DYSFUNCTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
MYOCARDIAL INFARCTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
PALPITATIONS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PERICARDIAL EFFUSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SINUS BRADYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	3 / 20 (15.00%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
SINUS TACHYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
AMNESIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
COGNITIVE DISTURBANCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
CONCENTRATION IMPAIRMENT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
DIZZINESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	1 / 13 (7.69%)
occurrences (all)	0	10	1
DYSGEUSIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	5 / 20 (25.00%)	1 / 13 (7.69%)
occurrences (all)	0	16	3
HEADACHE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	4 / 20 (20.00%)	0 / 13 (0.00%)
occurrences (all)	0	17	0
INTRACRANIAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
NER OTH ORTHOSTATISM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	4	4	4
NER OTH RESTLESS LEGS SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
NER OTH SCIATICA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
NER OTH SENSITIVITY STROBE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
NER OTH TASTE DISORDERS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

NER OTH TINGLING IN LEGS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
NER OTH WEAKNESS LEFT ARM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PARESTHESIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	7	0
PERIPHERAL MOTOR NEUROPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
RECURRENT LARYNGEAL NERVE PALSY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TREMOR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
PERIPHERAL SENSORY NEUROPATHY			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	6 / 20 (30.00%)	1 / 13 (7.69%)
occurrences (all)	0	13	1
Blood and lymphatic system disorders			
ANEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FEBRILE NEUTROPENIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
HEARING IMPAIRED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
VERTIGO			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
TINNITUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	9	0
Eye disorders			
CATARACT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
BLURRED VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	9 / 20 (45.00%)	1 / 13 (7.69%)
occurrences (all)	1	42	2
CONJUNCTIVITIS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
EYE OTH EYE DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	10	0
EYE OTH LEFT EYE VISION IMPAIRED DUE TO TUMOUR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
EYE OTH SMALL DISTURBANCES OF VISION ON WAKING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH ALTERED PERIPHERAL VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH BILATERAL MEIBOMITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH BURNING OF EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH BURNING SENSATION IN EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH COTTONWOOL SPOT			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH DECREASED VISUAL ACUITY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH DETERIORATING EYESIGHT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH DIPLOPIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH DOUBLE VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH EXOPHORIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	4 / 20 (20.00%)	0 / 13 (0.00%)
occurrences (all)	0	10	0
EYE OTH EYE STRAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH FLICKERING VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

EYE OTH GHOSTING WHEN GOING FROM DARK			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
EYE OTH INCREASED TENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH INTERMITTENT VISUAL DISTURBANCE/TUNNEL VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH ITCHY EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH PRESSURE ABOVE EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH MIOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH OCCULAR FATIGUE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH OVERCORRECTED MYOPIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH PALINOPSIA (AFTERIMAGES)			

alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH PERSISTENCE OF VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH PHOSPHENE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
EYE OTH LOSS OF VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH SMALL DISTURBANCES OF VISION ON WAKING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH SORE EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH STROBING VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH VISION DISORDERS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH VISUAL AFTERGLOW ON WAKING			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH VISUAL DISORDER (UNSTABLE IMAGES)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FLASHING LIGHTS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	3 / 20 (15.00%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
EYE OTH VISUAL DISTURBANCES ON WAKING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH VISUAL FIELD LOSS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH VISUAL IMPAIRMENT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	2	2	2
EYE OTH VISUAL LOSS OF 0,4			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
EYE OTH VISUAL PERSISTENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
EYE OTH VISUAL DISORDERS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FLOATERS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GLAUCOMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
KERATITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
OPTIC NERVE DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
PAPILLEDEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PHOTOPHOBIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
WATERING EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
STROBING VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorders			
DENTAL CARIES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
ABDOMINAL DISTENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	6 / 20 (30.00%)	1 / 13 (7.69%)
occurrences (all)	0	24	1
ASCITES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	3	3	3
BLOATING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	1 / 13 (7.69%)
occurrences (all)	0	5	1
CONSTIPATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	9 / 20 (45.00%)	7 / 13 (53.85%)
occurrences (all)	0	59	9
DIARRHEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	9 / 20 (45.00%)	3 / 13 (23.08%)
occurrences (all)	0	26	7
DRY MOUTH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
DYSPEPSIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	3 / 20 (15.00%)	0 / 13 (0.00%)
occurrences (all)	0	7	0
DYSPHAGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
ESOPHAGEAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ESOPHAGEAL ULCER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GAS OTH INDIGESTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	13	0
GAS OTH DIGESTIVE TROUBLE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GAS OTH ABDOMINAL ABCESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
GAS OTH ABDOMINAL CRAMP			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1

GAS OTH ACID REGURGITATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GAS OTH GINGIVITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ESOPHAGITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	3 / 20 (15.00%)	1 / 13 (7.69%)
occurrences (all)	0	11	3
GAS OTH MUCOSITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GAS OTH ODYNOPHAGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GAS OTH STOMACH CRAMPS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GAS OTH STOMACH TROUBLE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GAS OTH TYPE C GASTRITIS WITH ULCERATIVE LESIONS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
STOMACH PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
GASTROINTESTINAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HEMORRHOIDS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
MUCOSITIS ORAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
NAUSEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	11 / 20 (55.00%)	8 / 13 (61.54%)
occurrences (all)	0	44	11
RECTAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
GASTROESOPHAGEAL REFLUX DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
VOMITING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	8 / 20 (40.00%)	4 / 13 (30.77%)
occurrences (all)	0	25	5

Hepatobiliary disorders			
HEP OTH CIRRHOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
HEP OTH HEPATOPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
HEPATIC FAILURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
HEP OTH CHOLESTASIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
PHOTOSENSITIVITY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
ERYTHEMA MULTIFORME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HIRSUTISM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
HYPERHIDROSIS			

alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PERIORBITAL EDEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	3 / 20 (15.00%)	2 / 13 (15.38%)
occurrences (all)	0	5	4
PRURITUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	4 / 20 (20.00%)	0 / 13 (0.00%)
occurrences (all)	1	6	0
RASH MACULO-PAPULAR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	3 / 20 (15.00%)	0 / 13 (0.00%)
occurrences (all)	0	13	0
SKI OTH ACNE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH ACNE SPINE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH COLD HANDS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH CUTANEOUS ERYTHEMA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH HIVES alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
SKI OTH CUTANEOUS LESION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
SKI OTH CUTANEOUS RASH alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH ECZEMA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH ECZEMA (THIGH) alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
SKI OTH FACE HIVES alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
SKI OTH HAIR DEVELOPMENT alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

SKI OTH CUTANEOUS ERYTHEMA OF THE LEFT LOMBAR FOSSA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH LEFT KNEE SUBCUTANEOUS ABCESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH NAIL CHANGES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH PANNICULITIS LEFT THIGH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH PSORIATIC RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
SKI OTH RIGHT LOWER LEG RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH SEVERAL RED PAPULES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKI OTH SKIN RASH			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKIN HYPERPIGMENTATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKIN HYPOPIGMENTATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
URTICARIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	9	0
SKI OTH SEBORRHEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CHRONIC KIDNEY DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	0	3	3
HEMATURIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
REN OTH ACUTE RENAL INSUFICIENCY			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
REN OTH BLADDER PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
RENAL CYST(S)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
URINARY FREQUENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
URINARY INCONTINENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
URINARY URGENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
REN OTH ACUTE RENAL INSUFFICIENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Endocrine disorders			
END OTH DIABETES INSIPIDUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
END OTH LOW TESTOSTERONE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPOTHYROIDISM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	6 / 20 (30.00%)	0 / 13 (0.00%)
occurrences (all)	0	11	0
BACK PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	0	6	2
BONE PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BUTTOCK PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
CHEST WALL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	3	3	3
FLANK PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
GENERALIZED MUSCLE WEAKNESS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH CRAMPS LOWER LEG, LEFT alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH ACHING LEGS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH CRAMP alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	7	0
MUS OTH CRAMPS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH CRAMPS (INTERMITTENT) alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH CRAMPS IN THE CALF LEVEL alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH CRAMPS LEFT LEG alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
MUS OTH PAIN STERNUM alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

MUS OTH PAIN LEFT GROIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH PAIN OF LEFT AXILLA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH FIBROTIC LESION OUTSIDE THE LIVER alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH GROIN PAIN AMBILATERAL alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH HARD MASS IN THE CALF alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH INGUINAL PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH PAIN INGUINAL alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH LEFT LOIN PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH LEFT LOWER LIMB alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH LEG CRAMPS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH MUSCLE CRAMPS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
MUS OTH MUSCLES CRAMPS LEGS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH MUSCLES CRAMPS RIGHT LEG alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH INTERSCAPULAR PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH PAIN OF RIGHT HIP alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH PAIN RIGHT GROIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH PAIN UNDER RIGHT RIBS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

MUS OTH RIGHT SHOULDER TENDINITIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
MUS OTH SARCOPENIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
MUS OTH SHOULDER PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH UPPER LEG PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUSCLE WEAKNESS LOWER LIMB alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUSCLE WEAKNESS UPPER LIMB alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
MYALGIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	2 / 20 (10.00%)	1 / 13 (7.69%)
occurrences (all)	0	3	2
NECK PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	2	2	2
PAIN IN EXTREMITY alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MUS OTH SPASM IN BOTH LEGS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
BLADDER INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
BRONCHIAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
ENTEROCOLITIS INFECTIOUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
INF OTH BILATERAL VIRAL KERATOCONJUNCTIVITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH CANDIDA IN UPPER RESPIRATORY TRACT INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
INF OTH CHEST DRAIN SITE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH CHEST INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH INFLUENZA WITH FEVER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH COMMON COLD			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	2	2	0
INF OTH EAR INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
INF OTH HELICOBACTER PYLORI INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH INFECTION OF UNKNOWN ORIGIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH INFECTION PROBABLY VIRAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
INF OTH INFECTIOUS COLITIS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
INF OTH COLD SORE alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
INF OTH ORAL MYCOSIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	6	0
INF OTH ORAL THRUSH alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH PNEUMONIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH RESPIRATORY INFECTION alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	2	2	2
INF OTH RHINITIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH SEPTIC SHOCK alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH THRUSHESOPHAGITIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

INF OTH LOWER RESPIRATORY TRACT INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH ORAL CANDIDIASIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
INF OTH VIROSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
LUNG INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
OTITIS EXTERNA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
TOOTH INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	3 / 20 (15.00%)	0 / 13 (0.00%)
occurrences (all)	3	6	0
URINARY TRACT INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
SEPSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
ANOREXIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	2 / 20 (10.00%)	5 / 13 (38.46%)
occurrences (all)	1	6	13
DEHYDRATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	2 / 13 (15.38%)
occurrences (all)	0	3	3
HYPERGLYCEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
HYPOPHOSPHATEMIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MET OTH HYDROPIC DECOMPENSATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 3 (33.33%)	1 / 20 (5.00%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
MET OTH HYPERLIPIDEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
MET OTH LOW VITAMIN D			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
MET OTH SERUM IRON DECREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	0 / 20 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 3 (0.00%)	1 / 20 (5.00%)	0 / 13 (0.00%)
occurrences (all)	0	4	0

Non-serious adverse events	Alveolar soft part sarcoma (ASPS)	Clear cell sarcoma (CCSA)	Papillary renal cell carcinoma type 1 (PRCC)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 48 (100.00%)	34 / 34 (100.00%)	23 / 23 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
NEO OTH PAIN AFTER PATHOLOGICAL FRACTURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
NEO OTH PATHOLOGICAL FRACTURE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
TUMOR PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	6 / 34 (17.65%)	0 / 23 (0.00%)
occurrences (all)	2	15	0
Vascular disorders			
HEMATOMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
HOT FLASHES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	3	0	0
HYPERTENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 48 (18.75%)	5 / 34 (14.71%)	2 / 23 (8.70%)
occurrences (all)	19	11	4
HYPOTENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
LYMPHEDEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
VAS OTH THORACIC OUTLET			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
VAS OTH LEG VENOUS INSUFFICIENCY			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
VAS OTH PETECHIAE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
VAS OTH PULMONARY EMBOLI			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
THROMBOEMBOLIC EVENT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	3 / 34 (8.82%)	0 / 23 (0.00%)
occurrences (all)	1	4	0
Surgical and medical procedures			
SUR OTH POSTOPERATIVE PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
CHILLS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
EDEMA FACE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	6	0	3
EDEMA LIMBS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	8 / 48 (16.67%)	11 / 34 (32.35%)	11 / 23 (47.83%)
occurrences (all)	28	33	114
FATIGUE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	21 / 48 (43.75%)	20 / 34 (58.82%)	13 / 23 (56.52%)
occurrences (all)	126	93	164
FEVER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 48 (18.75%)	6 / 34 (17.65%)	2 / 23 (8.70%)
occurrences (all)	16	11	4
GEN OTH NIGHT SWEATS (INTERMITTENT)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
GEN OTH ANASARCA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
GEN OTH DETERIORATION OF GENERAL CONDITION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
GEN OTH INFLAMMATORY SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
GEN OTH NIGHT SWEAT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	5 / 34 (14.71%)	0 / 23 (0.00%)
occurrences (all)	0	7	0
GEN OTH NIGHT SWEATS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
FLU LIKE SYMPTOMS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	2 / 48 (4.17%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	2	4	0
GEN OTH PAINFUL SWELLING ABOVE RIGHT CLAVICLE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
GEN OTH SWEAT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
GEN OTH WORSENING OF GENERAL CONDITION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
MALAISE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
NON-CARDIAC CHEST PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 48 (10.42%)	3 / 34 (8.82%)	3 / 23 (13.04%)
occurrences (all)	5	8	5
PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences (all)	2	4	1
Immune system disorders			
ALLERGIC REACTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
IMM OTH ALLERGY OF FARINE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
BREAST PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
ERECTILE DYSFUNCTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	3	0
GYNECOMASTIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	10	0	0
IRREGULAR MENSTRUATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	3	0
PELVIC PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	1	0
VAGINAL DISCHARGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
VAGINAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	16 / 48 (33.33%)	10 / 34 (29.41%)	5 / 23 (21.74%)
occurrences (all)	47	23	17
DYSPNEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	8 / 48 (16.67%)	12 / 34 (35.29%)	7 / 23 (30.43%)
occurrences (all)	23	22	23
EPISTAXIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
HICCUPS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
HOARSENESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
MEDIASTINAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
ALLERGIC RHINITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	4
PHARYNGOLARYNGEAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
PLEURAL EFFUSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	2 / 23 (8.70%)
occurrences (all)	0	1	2

RES OTH PULMONARY DISCOMFORT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
PNEUMONITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	3 / 34 (8.82%)	0 / 23 (0.00%)
occurrences (all)	3	3	0
PNEUMOTHORAX			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
RES OTH BRONCHITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	2 / 23 (8.70%)
occurrences (all)	2	2	2
RES OTH BRONCHORRHEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
RES OTH CRIZOTINIB INDUCED INTERSTITIAL LUNG DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
RES OTH DECREASED BREATH SOUNDS IN A STRAIGHT BASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
RES OTH DECREASED BREATH SOUNDS IN RIGHT BASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
RES OTH HEMOPTYSIS			

alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 48 (6.25%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	3	0	0
RES OTH HEMOPTYSIS (PERIODIC)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
RES OTH INTERSTITIAL LUNG DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
RES OTH PHARYNGODYNIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
RES OTH PNEUMONIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
PLEURITIC PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	16	0
RES OTH TACHYPNEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
RES OTH TONSILLITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
RESPIRATORY FAILURE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
SORE THROAT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 48 (6.25%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	3	0	0
VOICE ALTERATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
WHEEZING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
INSOMNIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	2 / 23 (8.70%)
occurrences (all)	1	0	2
ANXIETY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
DEPRESSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	6	1	0
PSY OTH MOOD SWINGS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
PSY OTH SADNESS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
PSY OTH SLEEP DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Investigations			
BLOOD PROLACTIN ABNORMAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
CHOLESTEROL HIGH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
SERUM AMYLASE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
ELECTROCARDIOGRAM QT CORRECTED INTERVAL PROLONGED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	6 / 48 (12.50%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences (all)	9	3	2
GGT INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
INV OTH AGRANULOCYTOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
INV OTH CRP INCREASED			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
LIPASE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
CREATININE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
WEIGHT LOSS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
WEIGHT GAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 48 (8.33%)	4 / 34 (11.76%)	1 / 23 (4.35%)
occurrences (all)	10	18	1
WEIGHT LOSS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	10 / 48 (20.83%)	6 / 34 (17.65%)	1 / 23 (4.35%)
occurrences (all)	28	11	1
Injury, poisoning and procedural complications			
BURN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
FALL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
FRACTURE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 48 (2.08%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	2	3	0
INJ OTH BLOCKED CATHETER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
INJ OTH TICK BITE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Cardiac disorders			
CAR OTH BRADYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
CAR OTH CARDIAC SLOWING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
CAR OTH DECREASED HEART RATE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
CAR OTH TACHYSYSTOLIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
CAR OTH HEART MURMUR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
CAR OTH MITRAL MURMUR			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
CAR OTH SLOW-R-PROGRESSION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
CAR OTH TACHYCARDIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
CAR OTH DIASTOLIC DYSFUNCTION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
MYOCARDIAL INFARCTION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
PERICARDIAL EFFUSION alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
SINUS BRADYCARDIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 48 (10.42%)	2 / 34 (5.88%)	5 / 23 (21.74%)
occurrences (all)	22	22	61
SINUS TACHYCARDIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0

Nervous system disorders			
AMNESIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
COGNITIVE DISTURBANCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
CONCENTRATION IMPAIRMENT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
DIZZINESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 48 (14.58%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences (all)	22	5	1
DYSGEUSIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	8 / 48 (16.67%)	6 / 34 (17.65%)	5 / 23 (21.74%)
occurrences (all)	23	18	18
HEADACHE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	8 / 48 (16.67%)	3 / 34 (8.82%)	1 / 23 (4.35%)
occurrences (all)	24	8	9
INTRACRANIAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
LETHARGY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
NER OTH ORTHOSTATISM			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	4
NER OTH RESTLESS LEGS SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	2	2	0
NER OTH SCIATICA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
NER OTH SENSITIVITY STROBE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
NER OTH TASTE DISORDERS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
NER OTH TINGLING IN LEGS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
NER OTH WEAKNESS LEFT ARM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
PARESTHESIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	5	17	0
PERIPHERAL MOTOR NEUROPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

RECURRENT LARYNGEAL NERVE PALSY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
SOMNOLENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	0	4	0
SYNCOPE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
TREMOR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 48 (8.33%)	1 / 34 (2.94%)	2 / 23 (8.70%)
occurrences (all)	22	1	8
Blood and lymphatic system disorders			
ANEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
FEBRILE NEUTROPENIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
HEARING IMPAIRED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
VERTIGO			

alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
TINNITUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
CATARACT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
BLURRED VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	24 / 48 (50.00%)	8 / 34 (23.53%)	8 / 23 (34.78%)
occurrences (all)	83	15	34
CONJUNCTIVITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH EYE DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH LEFT EYE VISION IMPAIRED DUE TO TUMOUR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
EYE OTH SMALL DISTURBANCES OF VISION ON WAKING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
EYE OTH ALTERED PERIPHERAL VISION			

alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	6	0
EYE OTH BILATERAL MEIBOMITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH BURNING OF EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
EYE OTH BURNING SENSATION IN EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	7	0
EYE OTH COTTONWOOL SPOT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
EYE OTH DECREASED VISUAL ACUITY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH DETERIORATING EYESIGHT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH DIPLOPIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
EYE OTH DOUBLE VISION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	5	0	0
EYE OTH EXOPHORIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
DRY EYE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH EYE STRAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH FLICKERING VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
EYE OTH GHOSTING WHEN GOING FROM DARK			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH INCREASED TENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
EYE OTH INTERMITTENT VISUAL DISTURBANCE/TUNNEL VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	14	0
EYE OTH ITCHY EYES			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
EYE OTH PRESSURE ABOVE EYES alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH MIOSIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH OCCULAR FATIGUE alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH OVERCORRECTED MYOPIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH PALINOPSIA (AFTERIMAGES) alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	22	0	0
EYE OTH PERSISTENCE OF VISION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	3
EYE OTH PHOSPHENE alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH LOSS OF VISION alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	4	0	0

EYE OTH SMALL DISTURBANCES OF VISION ON WAKING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	11
EYE OTH SORE EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
EYE OTH STROBING VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	22
EYE OTH VISION DISORDERS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
EYE OTH VISUAL AFTERGLOW ON WAKING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
EYE OTH VISUAL DISORDER (UNSTABLE IMAGES)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	4	0
FLASHING LIGHTS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 48 (14.58%)	3 / 34 (8.82%)	1 / 23 (4.35%)
occurrences (all)	64	8	1
EYE OTH VISUAL DISTURBANCES ON WAKING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
EYE OTH VISUAL FIELD LOSS			

alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	3	0	0
EYE OTH VISUAL IMPAIRMENT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	2
EYE OTH VISUAL LOSS OF 0,4			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
EYE OTH VISUAL PERSISTENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	5
EYE OTH VISUAL DISORDERS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	17
FLOATERS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 48 (6.25%)	0 / 34 (0.00%)	3 / 23 (13.04%)
occurrences (all)	17	0	32
GLAUCOMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
KERATITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	3
OPTIC NERVE DISORDER			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	4 / 48 (8.33%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	13	1	0
PAPILLEDEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
PHOTOPHOBIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
WATERING EYES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
STROBING VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
DENTAL CARIES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	2	0
ABDOMINAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 48 (18.75%)	7 / 34 (20.59%)	5 / 23 (21.74%)
occurrences (all)	20	23	9
ASCITES			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	3
BLOATING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
CONSTIPATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	18 / 48 (37.50%)	15 / 34 (44.12%)	12 / 23 (52.17%)
occurrences (all)	68	36	40
DIARRHEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	20 / 48 (41.67%)	12 / 34 (35.29%)	10 / 23 (43.48%)
occurrences (all)	124	35	137
DRY MOUTH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
DYSPEPSIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	6 / 48 (12.50%)	4 / 34 (11.76%)	0 / 23 (0.00%)
occurrences (all)	14	8	0
DYSPHAGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	0	6	0
ESOPHAGEAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 48 (6.25%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	3	0	0
ESOPHAGEAL ULCER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0

GAS OTH INDIGESTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
FLATULENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	4	3	0
GAS OTH DIGESTIVE TROUBLE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
GAS OTH ABDOMINAL ABCESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
GAS OTH ABDOMINAL CRAMP			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
GAS OTH ACID REGURGITATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
GAS OTH GINGIVITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
ESOPHAGITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 48 (6.25%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	3	1	2
GAS OTH MUCOSITIS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
GAS OTH ODYNOPHAGIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
GAS OTH STOMACH CRAMPS alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	5	0	0
GAS OTH STOMACH TROUBLE alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
GAS OTH TYPE C GASTRITIS WITH ULCERATIVE LESIONS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
GASTRITIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	2	0	2
STOMACH PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 48 (6.25%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	6	2	1
GASTROINTESTINAL PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	4	0	0
HEMORRHOIDS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

MUCOSITIS ORAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	4	0	2
NAUSEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	34 / 48 (70.83%)	20 / 34 (58.82%)	11 / 23 (47.83%)
occurrences (all)	97	57	29
RECTAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
GASTROESOPHAGEAL REFLUX DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	2	2	0
VOMITING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	24 / 48 (50.00%)	15 / 34 (44.12%)	4 / 23 (17.39%)
occurrences (all)	63	24	5
Hepatobiliary disorders			
HEP OTH CIRRHOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
HEP OTH HEPATOPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
HEPATIC FAILURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
HEP OTH CHOLESTASIS			
alternative dictionary used: CTCAE			

4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
PHOTOSENSITIVITY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	5	1	0
DRY SKIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	2 / 34 (5.88%)	2 / 23 (8.70%)
occurrences (all)	2	3	13
ERYTHEMA MULTIFORME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	6	0	0
HIRSUTISM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
PERIORBITAL EDEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	3	0
ALOPECIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	2 / 48 (4.17%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	13	2	0
PRURITUS alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 48 (8.33%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences (all)	11	2	1
RASH MACULO-PAPULAR alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 48 (14.58%)	3 / 34 (8.82%)	3 / 23 (13.04%)
occurrences (all)	13	8	8
SKI OTH ACNE alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	4
SKI OTH ACNE SPINE alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
SKI OTH COLD HANDS alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
SKI OTH CUTANEOUS ERYTHEMA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
SKI OTH HIVES alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
SKI OTH CUTANEOUS LESION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

SKI OTH CUTANEOUS RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	3
SKI OTH ECZEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
SKI OTH ECZEMA (THIGH)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
SKI OTH FACE HIVES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
SKI OTH HAIR DEVELOPMENT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
SKI OTH CUTANEOUS ERYTHEMA OF THE LEFT LOMBAR FOSSA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
SKI OTH LEFT KNEE SUBCUTANEOUS ABCESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
SKI OTH NAIL CHANGES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	10
SKI OTH PANNICULITIS LEFT THIGH			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
SKI OTH PSORIATIC RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	7
SKI OTH RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
SKI OTH RIGHT LOWER LEG RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	10	0
SKI OTH SEVERAL RED PAPULES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
SKI OTH SKIN RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
SKIN HYPERPIGMENTATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
SKIN HYPOPIGMENTATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0

SKI OTH SEBORRHEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	11
CHRONIC KIDNEY DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
HEMATURIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
REN OTH ACUTE RENAL INSUFICIENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
REN OTH BLADDER PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
RENAL CYST(S)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	59
URINARY FREQUENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	2
URINARY INCONTINENCE			
alternative dictionary used: CTCAE			

4			
subjects affected / exposed	2 / 48 (4.17%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	3	0	3
URINARY URGENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	3
REN OTH ACUTE RENAL INSUFFICIENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Endocrine disorders			
END OTH DIABETES INSIPIDUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
END OTH LOW TESTOSTERONE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	7	0	0
HYPOTHYROIDISM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 48 (10.42%)	4 / 34 (11.76%)	2 / 23 (8.70%)
occurrences (all)	15	19	16
BACK PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	6 / 48 (12.50%)	3 / 34 (8.82%)	2 / 23 (8.70%)
occurrences (all)	8	7	2
BONE PAIN			

alternative dictionary used: CTCAE 4			
subjects affected / exposed	6 / 48 (12.50%)	3 / 34 (8.82%)	1 / 23 (4.35%)
occurrences (all)	14	6	7
BUTTOCK PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
CHEST WALL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	3
FLANK PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
GENERALIZED MUSCLE WEAKNESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
MUS OTH CRAMPS LOWER LEG, LEFT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
MUS OTH ACHING LEGS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
MUS OTH CRAMP			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
MUS OTH CRAMPS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	4
MUS OTH CRAMPS (INTERMITTENT)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MUS OTH CRAMPS IN THE CALF LEVEL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	15
MUS OTH CRAMPS LEFT LEG			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MUS OTH PAIN STERNUM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
MUS OTH PAIN LEFT GROIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	3	0	0
MUS OTH PAIN OF LEFT AXILLA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
MUS OTH FIBROTIC LESION OUTSIDE THE LIVER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MUS OTH GROIN PAIN AMBILATERAL			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
MUS OTH HARD MASS IN THE CALF			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MUS OTH INGUINAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
MUS OTH PAIN INGUINAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
MUS OTH LEFT LOIN PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MUS OTH LEFT LOWER LIMB			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
MUS OTH LEG CRAMPS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
MUS OTH MUSCLE CRAMPS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
MUS OTH MUSCLES CRAMPS LEGS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1

MUS OTH MUSCLES CRAMPS RIGHT LEG			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
MUS OTH INTERSCAPULAR PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MUS OTH PAIN OF RIGHT HIP			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
MUS OTH PAIN RIGHT GROIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
MUS OTH PAIN UNDER RIGHT RIBS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MUS OTH RIGHT SHOULDER TENDINITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
MUS OTH SARCOPENIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
MUS OTH SHOULDER PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MUS OTH UPPER LEG PAIN			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
MUSCLE WEAKNESS LOWER LIMB alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	8	0	0
MUSCLE WEAKNESS UPPER LIMB alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
MYALGIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 48 (6.25%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	5	0	0
NECK PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	7	2	2
PAIN IN EXTREMITY alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 48 (8.33%)	3 / 34 (8.82%)	0 / 23 (0.00%)
occurrences (all)	17	4	0
MUS OTH SPASM IN BOTH LEGS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BLADDER INFECTION alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL INFECTION alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
BRONCHIAL INFECTION alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	1	1	1
ENTEROCOLITIS INFECTIOUS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
INF OTH BILATERAL VIRAL KERATOCONJUNCTIVITIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
INF OTH CANDIDA IN UPPER RESPIRATORY TRACT INFECTION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
INF OTH CHEST DRAIN SITE alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
INF OTH CHEST INFECTION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
INF OTH INFLUENZA WITH FEVER alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
INF OTH COMMON COLD alternative dictionary used: CTCAE 4			

subjects affected / exposed	5 / 48 (10.42%)	5 / 34 (14.71%)	2 / 23 (8.70%)
occurrences (all)	11	6	10
INF OTH EAR INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
INF OTH HELICOBACTER PYLORI INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
INF OTH INFECTION OF UNKNOWN ORIGIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
INF OTH INFECTION PROBABLY VIRAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
INF OTH INFECTIOUS COLITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
INF OTH COLD SORE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
INF OTH ORAL MYCOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
INF OTH ORAL THRUSH			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
INF OTH PNEUMONIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
INF OTH RESPIRATORY INFECTION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
INF OTH RHINITIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
INF OTH SEPTIC SHOCK alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
INF OTH THRUSHESOPHAGITIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
INF OTH LOWER RESPIRATORY TRACT INFECTION alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
INF OTH ORAL CANDIDIASIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
INF OTH VIROSIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0

LARYNGITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
LUNG INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	3	1	1
OTITIS EXTERNA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
PHARYNGITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
SINUSITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
SKIN INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	16	0	0
TOOTH INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
UPPER RESPIRATORY INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	3 / 34 (8.82%)	0 / 23 (0.00%)
occurrences (all)	2	3	0
URINARY TRACT INFECTION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 48 (2.08%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
SEPSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
ANOREXIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	12 / 48 (25.00%)	10 / 34 (29.41%)	5 / 23 (21.74%)
occurrences (all)	34	40	16
DEHYDRATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 48 (4.17%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
HYPERGLYCEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MET OTH HYDROPIC DECOMPENSATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
MET OTH HYPERLIPIDEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
MET OTH LOW VITAMIN D			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
MET OTH SERUM IRON DECREASED alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
HYPOMAGNESEMIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 48 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 March 2014	After one year of recruitment, it appears that the recruitment is faster and that the prevalence of ALK/MET+ patients is higher than expected for part of the cohorts (almost 90% in at least 2 cohorts). In addition, because the whole treatment duration is defined as assessment period for response evaluation, response in some patients requires a very long observation time in particular as some patients may remain in stable disease for a long period and then switch very late to either progression (best response being then SD) or response (best response being then response). Therefore the protocol was amendment to not stop the recruitment once stage I was reached.
26 March 2015	The objective of this amendment is to permit young patient population (below 15 yo) to be enrolled in this protocol.
06 February 2017	The following changes were made: -Background section -Eligibility criteria (mainly focusing on restriction for cardiac events) - Clinically normal cardiac function based on the institutional lower limit of normal (LVEF assessed by MUGA or ECHO) and normal 12 lead ECG. - Machine-read ECG QTcF interval ≤470 msec. Periodic monitoring of cardiac function will be performed by ECG and LVEF at baseline and for all patients on treatment: o 12 lead ECG then triplicate set on Day 1 of Cycles 1, 2 & 3 and thereafter every 4 cycles. o LVEF every 3 cycles , more frequently if clinically indicated and at the end of the treatment
09 February 2021	Pfizer notified us recently about an important safety information regarding ocular toxicity with Xalkori® (crizotinib) in patients with anaplastic large cell lymphoma (ALCL). In a study of 121 patients who were ≤ 21 years of age treated with Xalkori®, 26 patients with ALCL were included and vision disorders were reported in 65% of these patients. The most common visual symptoms were blurred vision and visual impairment with median onset of approximately 1 week. Other visual symptoms included photopsia, vitreous floaters, and photophobia.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported