



Clinical trial results:

Empirical versus pre-emptive (diagnostic-driven) antifungal therapy of patients treated for haematological malignancies or receiving an allogeneic stem cell transplant. A therapeutic open label phase III strategy study of the EORTC Infectious Diseases and Leukemia Groups
Summary

EudraCT number	2010-020814-27
Trial protocol	DE NL BE CZ SK
Global end of trial date	04 April 2019

Results information

Result version number	v1 (current)
This version publication date	12 February 2021
First version publication date	12 February 2021

Trial information

Trial identification

Sponsor protocol code	65091-06093
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01288378
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	European Organisation for Research and Treatment of Cancer
Sponsor organisation address	Avenue E Mounier 83/11, Brussels, Belgium, 1200
Public contact	Regulatory Affairs Department, European Organisation for Research and Treatment of Cancer, 32 27741611, regulatory@eortc.org
Scientific contact	Regulatory Affairs Department, European Organisation for Research and Treatment of Cancer, 32 27741611, regulatory@eortc.org

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	23 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 December 2015
Global end of trial reached?	Yes
Global end of trial date	04 April 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial is to compare two strategies, namely an empirical approach (fever driven) (EAT, arm A) versus pre-emptive (diagnostic driven) (PAT, Arm B) approach, for starting antifungal therapy (with caspofungin) for managing patients treated with chemotherapy for attaining remission induction of acute myeloid leukemia or myelodysplastic syndrome or myeloablation to prepare for an allogeneic HSCT, by assessing the survival rates 42 days (6 weeks) after initial randomization. The intent is to show the non-inferiority of the pre-emptive approach.

Protection of trial subjects:

The responsible investigator ensures 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 conducted according to the ICH Harmonized Tripartite Guideline on Good Clinical Practice (ICH-GCP, available online at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf).

The protocol was approved by the competent ethics committee(s) as required by the applicable national legislation.

Background therapy:

Patients in this study are treated with chemotherapy for attaining remission induction of acute myeloid leukemia or myelodysplastic syndrome or myeloablation to prepare for an allogeneic HSCT

Evidence for comparator:

Early antifungal therapy and clinical awareness of the possibility of an invasive fungal infection remain crucial prerequisites to avoid the confrontation with a stage of infection beyond a reasonable chance of cure. By consequence, treatment is often commenced on an empirical basis, i.e. for fever not responding to adequate antibacterial therapy. The perceived need for systematically active antifungal therapy may vary between 10% and 80% in different centers. This strategy is based on few studies, that are now cited as gold standards but which comprised only a limited number of patients. Nevertheless, after publication of these studies, the empirical use of broad-spectrum antifungals in persistently febrile neutropenic cancer patients has become a more or less generally accepted strategy.

Consequently, an increasing number of investigators institute broad-spectrum antifungal for neutropenic patients whose fever persists for 3 or more days. This probably reflects a common attitude particularly in North-America, where two-thirds of the patients in prophylactic studies on fluconazole for acute leukemia and bone marrow transplants received empirical broad-spectrum antifungals to, whereas in a large European study in a similar population only 20% of the patients received empirical intravenous antifungal drugs. Indeed, in Europe, most centers will commence systemic empirical antifungal therapy after 5 days of fever not responding to antibiotics, while others are even more selective being guided by clinical, radiological and microbiological parameters suggestive of an invasive fungal infection. Therefore, the question of the optimal time point to start antifungal treatment remains. It seems warranted to try to establish more rational grounds to initiate antifungal therapy in persistently febrile neutropenic patients. The drug of choice for such a pre-emptive approach remains to be determined, but caspofungin may prove to be a good candidate.

Actual start date of recruitment	09 March 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	Netherlands: 52
Country: Number of subjects enrolled	Slovakia: 16
Country: Number of subjects enrolled	Belgium: 221
Country: Number of subjects enrolled	Czechia: 19
Country: Number of subjects enrolled	France: 195
Country: Number of subjects enrolled	Germany: 53
Worldwide total number of subjects	556
EEA total number of subjects	556

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	445
From 65 to 84 years	111
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

556 patients randomized between March 09, 2012 and September 30, 2015 by 15 institutions in 6 countries.

Pre-assignment

Screening details:

- Age 18 or older
- planning to start remission induction chemotherapy for acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS)
- Planned hospital admission for the duration of the neutropenic phase ($ANC < 0.5 \times 10^9 /L$).
- No previous or current history of proven or probable IFD.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	EAT arm

Arm description:

Empirical antifungal treatment

Empirical therapy will be initiated in case of:

presence of unexplained persistent fever* refractory to 4 full days of broad-spectrum antibacterial therapy with any of the following regimens: ceftazidime, cefepime, piperacillin/tazobactam, imipenem-cilastatin, or meropenem, alone or combined with an aminoglycoside or a glycopeptide
or

new fever occurring >2 days after resolution of a first fever while continuing broad-spectrum antibacterial therapy as defined above for which no (obvious) cause has been documented and fungal infection cannot be excluded.

* Definition of fever: single temperature $> 38.5^{\circ}C$ or $> 38^{\circ}C$ on two or more consecutive occasions during one two-hour period (ICHS Consensus definitions).

Definition of defervescence: maximum temperature $< 38^{\circ}C$ for at least two consecutive days.

Arm type	Active comparator
Investigational medicinal product name	Caspofungin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

caspofungin will be given by intravenous route, according to the recommendations of the Summary of Product Characteristics (SmPC) of caspofungin

(http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000379/WC500021033.pdf), at a 70 mg loading dose on day 1 of

antifungal therapy, followed by 50 mg once a day thereafter unless the body weight exceeds 80 kg in which case the dose will remain at 70 mg/day.

Each 50-mg (or 70-mg) infusion of caspofungin will be prepared daily. The appropriate quantities of

Arm title	PAT arm
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Arm description:

Pre-emptive antifungal therapy

Criteria for starting study therapy in Arm B are the following (at least one):

single plasma or serum galactomannan ELISA with index > 0.5 .

new pulmonary infiltrate on chest-X ray and IFD cannot be readily excluded.

new dense well circumscribed lesion(s) with or without a halo sign, on a CT scan, consistent with IFD.

Aspergillus sp. recovered by culture from sputum.

Arm type	Experimental
Investigational medicinal product name	Caspofungin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

caspofungin will be given by intravenous route, according to the recommendations of the Summary of Product Characteristics (SmPC) of caspofungin

(http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000379/WC500021033.pdf), at a 70 mg loading dose on day 1 of

antifungal therapy, followed by 50 mg once a day thereafter unless the body weight exceeds 80 kg in which case the dose will remain at 70 mg/day.

Each 50-mg (or 70-mg) infusion of caspofungin will be prepared daily. The appropriate quantities of

Number of subjects in period 1	EAT arm	PAT arm
Started	279	277
Completed	279	277

Baseline characteristics

Reporting groups

Reporting group title	EAT arm
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Reporting group description:

Empirical antifungal treatment

Empirical therapy will be initiated in case of:

presence of unexplained persistent fever* refractory to 4 full days of broad-spectrum antibacterial therapy with any of the following regimens: ceftazidime, cefepime, piperacillin/tazobactam, imipenem-cilastatin, or meropenem, alone or combined with an aminoglycoside or a glycopeptide

or

new fever occurring >2 days after resolution of a first fever while continuing broad-spectrum antibacterial therapy as defined above for which no (obvious) cause has been documented and fungal infection cannot be excluded.

* Definition of fever: single temperature > 38.5°C or > 38°C on two or more consecutive occasions during one two-hour period (ICHS Consensus definitions).

Definition of defervescence: maximum temperature < 38°C for at least two consecutive days.

Reporting group title	PAT arm
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Reporting group description:

Pre-emptive antifungal therapy

Criteria for starting study therapy in Arm B are the following (at least one):

single plasma or serum galactomannan ELISA with index > 0.5.

new pulmonary infiltrate on chest-X ray and IFD cannot be readily excluded.

new dense well circumscribed lesion(s) with or without a halo sign, on a CT scan, consistent with IFD.

Aspergillus sp. recovered by culture from sputum.

Reporting group values	EAT arm	PAT arm	Total
Number of subjects	279	277	556
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	214	216	430
From 65-84 years	65	61	126
85 years and over	0	0	0
Age continuous			
Units: years			
median	54	53	
full range (min-max)	18 to 78	18 to 77	-
Gender categorical			
Units: Subjects			
Female	124	117	241
Male	155	160	315
Underlying disease			
Units: Subjects			
De novo AML	187	189	376
Secondary AML	49	47	96
De novo MDS	15	14	29

Secondary MDS	2	3	5
Other	26	24	50
AML risk classification			
AML risk classification in AML patients			
Units: Subjects			
Favorable risk	46	45	91
Intermediate-1 risk	56	57	113
Intermediate-2 risk	39	51	90
Unfavorable risk	90	76	166
Unknown	5	7	12
non-AML patients	43	41	84

Subject analysis sets

Subject analysis set title	Modified ITT population - EAT arm
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Eligible randomized patients - EAT arm	
Subject analysis set title	Modified ITT population - PAT arm
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Eligible randomized patients - PAT arm	

Reporting group values	Modified ITT population - EAT arm	Modified ITT population - PAT arm	
Number of subjects	275	274	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	210	215	
From 65-84 years	65	59	
85 years and over	0	0	
Age continuous			
Units: years			
median	54	52.5	
full range (min-max)	18 to 78	18 to 77	
Gender categorical			
Units: Subjects			
Female	122	116	
Male	153	158	
Underlying disease			
Units: Subjects			
De novo AML	184	186	
Secondary AML	48	47	
De novo MDS	15	14	

Secondary MDS	2	3	
Other	26	24	
AML risk classification			
AML risk classification in AML patients			
Units: Subjects			
Favorable risk	45	45	
Intermediate-1 risk	56	57	
Intermediate-2 risk	39	50	
Unfavorable risk	87	74	
Unknown	5	7	
non-AML patients	43	41	

End points

End points reporting groups

Reporting group title	EAT arm
Reporting group description: Empirical antifungal treatment Empirical therapy will be initiated in case of: presence of unexplained persistent fever* refractory to 4 full days of broad-spectrum antibacterial therapy with any of the following regimens: ceftazidime, cefepime, piperacillin/tazobactam, imipenem-cilastatin, or meropenem, alone or combined with an aminoglycoside or a glycopeptide or new fever occurring >2 days after resolution of a first fever while continuing broad-spectrum antibacterial therapy as defined above for which no (obvious) cause has been documented and fungal infection cannot be excluded. * Definition of fever: single temperature > 38.5°C or > 38°C on two or more consecutive occasions during one two-hour period (ICHS Consensus definitions). Definition of defervescence: maximum temperature < 38°C for at least two consecutive days.	
Reporting group title	PAT arm
Reporting group description: Pre-emptive antifungal therapy Criteria for starting study therapy in Arm B are the following (at least one): single plasma or serum galactomannan ELISA with index > 0.5. new pulmonary infiltrate on chest-X ray and IFD cannot be readily excluded. new dense well circumscribed lesion(s) with or without a halo sign, on a CT scan, consistent with IFD. Aspergillus sp. recovered by culture from sputum.	
Subject analysis set title	Modified ITT population - EAT arm
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Eligible randomized patients - EAT arm	
Subject analysis set title	Modified ITT population - PAT arm
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Eligible randomized patients - PAT arm	

Primary: Overall survival at 42 days

End point title	Overall survival at 42 days
End point description:	
End point type	Primary
End point timeframe: Overall survival at 42 days i.e. 6 weeks after randomization, estimated using the KM method	

End point values	Modified ITT population - EAT arm	Modified ITT population - PAT arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	275	274		
Units: percentage				
number (confidence interval 95%)	93.1 (89.3 to 95.5)	96.7 (93.8 to 98.3)		

Attachments (see zip file)	Overall survival/OS.png
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Statistical analyses

Statistical analysis title	Primary analysis
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Statistical analysis description:

The null hypothesis to be tested is:

$H_0: (1-SPAT)/(1-SEAT) \geq RR$

Versus the alternative hypothesis

$H_1: (1-SPAT)/(1-SEAT) < RR$

Where RR is the greatest relative risk for death we can accept for claiming that the PAT arm is non-inferior to the EAT arm.

The null hypothesis will be rejected if the upper bound of the 95% confidence interval for $(1-SPAT)/(1-SEAT)$ is < 1.62 .

Comparison groups	Modified ITT population - EAT arm v Modified ITT population - PAT arm
Number of subjects included in analysis	549
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
Parameter estimate	$(1-SPAT)/(1-SEAT)$
Point estimate	0.5
Confidence interval	
level	95 %
sides	1-sided
upper limit	1.4

Notes:

[1] - If the null hypothesis is rejected, the conclusion of non-inferiority of the pre-emptive arm will be reached.

The upper bound is $1.4 < 1.62$ so the null hypothesis can be rejected and we can conclude the pre-emptive arm is non-inferior compared to the empirical arm.

Secondary: Development of proven or probable IFD during the 42 (6 weeks) following randomization.

End point title	Development of proven or probable IFD during the 42 (6 weeks) following randomization.
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End point description:

End point type	Secondary
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End point timeframe:

Development of proven or probable IFD during the 42 (6 weeks) following randomization.

End point values	Modified ITT population - EAT arm	Modified ITT population - PAT arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	275	274		
Units: Number of subjects				
Proven	3	5		
Probable	12	13		
Possible	13	22		
IFD cannot be excluded	23	34		
no IFD	224	200		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival at 84 days

End point title	Overall survival at 84 days
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End point description:

End point type	Secondary
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End point timeframe:

Overall survival at 84 days after randomization is estimated using the KM method

End point values	Modified ITT population - EAT arm	Modified ITT population - PAT arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	275	274		
Units: Percentage				
number (confidence interval 95%)	90.5 (86.3 to 93.4)	92.6 (88.8 to 95.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Development of proven or probable IFD during the 84 days following randomization.

End point title	Development of proven or probable IFD during the 84 days following randomization.
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End point description:

End point type	Secondary
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End point timeframe:

Development of proven or probable IFD during the 84 days following randomization.

End point values	Modified ITT population - EAT arm	Modified ITT population - PAT arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	275	274		
Units: Number of subjects				
Proven	4	7		
Probable	14	14		
Possible	14	28		
IFD cannot be excluded	27	35		
No IFD	216	190		

Statistical analyses

No statistical analyses for this end point

Secondary: Survival free of fungal infection 42 days (6 weeks) following randomization.

End point title	Survival free of fungal infection 42 days (6 weeks) following randomization.
End point description:	
Survival will be computed from randomization. Free of fungal infection means absence of proven or probable fungal infection, estimated using the KM method	
End point type	Secondary
End point timeframe:	
Survival free of fungal infection 42 days (6 weeks) following randomization.	

End point values	Modified ITT population - EAT arm	Modified ITT population - PAT arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	275	274		
Units: Percentage				
number (confidence interval 95%)	92.1 (88.1 to 94.8)	94.6 (91.0 to 96.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Survival free of fungal infection 84 days (12 weeks) following randomization.

End point title	Survival free of fungal infection 84 days (12 weeks) following
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randomization.

End point description:

Survival will be computed from randomization. Free of fungal infection means absence of proven or probable fungal infection using the KM method

End point type	Secondary
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End point timeframe:

Survival free of fungal infection 84 days (12 weeks) following randomization.

End point values	Modified ITT population - EAT arm	Modified ITT population - PAT arm		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	275	274		
Units: Percentage				
number (confidence interval 95%)	89.1 (83.8 to 92.7)	92.6 (88.1 to 95.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected till day 84 after randomization.

Adverse event reporting additional description:

CRF for AEs contained pre-specified items + additional boxes for all "other" AEs.

Non-SAEs have not been collected specifically, all AEs will be reported in non-SAE section. Note that AEs related to hematology and biochemistry lab values were not systematically collected and are not included in the tables below.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	PAT arm
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Reporting group description:

PAT arm

Reporting group title	EAT arm
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Reporting group description:

EAT arm

Serious adverse events	PAT arm	EAT arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	59 / 277 (21.30%)	71 / 279 (25.45%)	
number of deaths (all causes)	22	30	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ACUTE MYELOID LEUKAEMIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
HAEMATOLOGICAL MALIGNANCY			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
LEUKAEMIA RECURRENT			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST TRANSPLANT LYMPHOPROLIFERATIVE DISORDER			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
HAEMORRHAGE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTENSION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
VENOUS THROMBOSIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
DISEASE PROGRESSION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
EUTHANASIA			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
GENERAL PHYSICAL HEALTH DETERIORATION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTHERMIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	6 / 277 (2.17%)	6 / 279 (2.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 6	0 / 4	
PYREXIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
ANAPHYLACTIC REACTION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GRAFT VERSUS HOST DISEASE			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
GRAFT VERSUS HOST DISEASE IN SKIN			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMMUNE RECONSTITUTION INFLAMMATORY SYNDROME			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY DISTRESS SYNDROME			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	4 / 279 (1.43%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
ACUTE RESPIRATORY FAILURE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
ALVEOLITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASTHMA			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSпноEA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERCAPNIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOXIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFILTRATION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY ALVEOLAR HAEMORRHAGE			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY HAEMORRHAGE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY OEDEMA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
RESPIRATORY DISTRESS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY FAILURE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Investigations			
ELECTROCARDIOGRAM QT PROLONGED			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
FALL			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL STOMA NECROSIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEAD INJURY			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBDURAL HAEMATOMA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
TOXICITY TO VARIOUS AGENTS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
APLASIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ACUTE MYOCARDIAL INFARCTION			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARRHYTHMIA SUPRAVENTRICULAR alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FIBRILLATION alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FLUTTER alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ARREST alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
CARDIAC FAILURE alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
CARDIAC FAILURE ACUTE alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

CARDIOGENIC SHOCK alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 277 (0.36%) 0 / 1 0 / 1	0 / 279 (0.00%) 0 / 0 0 / 0		
CARDIOPULMONARY FAILURE alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 277 (0.36%) 0 / 1 0 / 0	0 / 279 (0.00%) 0 / 0 0 / 0		
LEFT VENTRICULAR FAILURE alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 277 (0.36%) 0 / 1 0 / 0	0 / 279 (0.00%) 0 / 0 0 / 0		
MYOCARDITIS alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 277 (0.00%) 0 / 0 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 0		
SINUS TACHYCARDIA alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 277 (0.00%) 0 / 0 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 0		
TACHYCARDIA alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 277 (0.36%) 0 / 1 0 / 0	0 / 279 (0.00%) 0 / 0 0 / 0		
VENTRICULAR FIBRILLATION alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
CEREBRAL HAEMORRHAGE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
COMA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
ENCEPHALOPATHY			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPILEPSY			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGIC STROKE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
HEADACHE			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
LOSS OF CONSCIOUSNESS				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
METABOLIC ENCEPHALOPATHY				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 1		
MYOCLONUS				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
NEUROLOGICAL DECOMPENSATION				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
POSTERIOR REVERSIBLE ENCEPHALOPATHY SYNDROME				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PRESYNCOPE				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBARACHNOID HAEMORRHAGE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Blood and lymphatic system disorders			
ANAEMIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DISSEMINATED INTRAVASCULAR COAGULATION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
FEBRILE NEUTROPENIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 277 (1.44%)	5 / 279 (1.79%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
LEUKOCYTOSIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCYTOPENIA			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	4 / 279 (1.43%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
OPTIC NERVE INFARCTION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VISUAL IMPAIRMENT			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANAL FISTULA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANORECTAL DISORDER			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
COLITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	3 / 279 (1.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
DIARRHOEA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTERITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOLITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL ISCHAEMIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINE PERFORATION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

MELAENA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	3 / 279 (1.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
OESOPHAGITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
PANCREATITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL OBSTRUCTION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBILEUS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER GASTROINTESTINAL HAEMORRHAGE			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLECYSTITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRUG-INDUCED LIVER INJURY			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
HEPATIC FAILURE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
HEPATITIS CHOLESTATIC			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATOCELLULAR INJURY			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATOTOXICITY			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENOOCCLUSIVE LIVER DISEASE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOXIC SKIN ERUPTION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	4 / 277 (1.44%)	6 / 279 (2.15%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
CYSTITIS HAEMORRHAGIC			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATURIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
TRISMUS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
ACARODERMATITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
APPENDICITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASPERGILLUS INFECTION			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERAEMIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
BACTERIAL SEPSIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
BRAIN ABSCESS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHOPULMONARY ASPERGILLOSIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CENTRAL NERVOUS SYSTEM INFECTION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL ASPERGILLOSIS			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
CLOSTRIDIUM DIFFICILE COLITIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYTOMEGALOVIRUS INFECTION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYTOMEGALOVIRUS INFECTION REACTIVATION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED INFECTION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED SEPSIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOCARDITIS			
alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOCCAL BACTERAEMIA alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOCCAL INFECTION alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPSTEIN-BARR VIRUS INFECTION REACTIVATION alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA BACTERAEMIA alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA SEPSIS alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEBRILE INFECTION alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
FUNGAL INFECTION				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 1	0 / 1		
FUSARIUM INFECTION				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
GEOTRICHUM INFECTION				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
HERPES SIMPLEX ENCEPHALITIS				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
HERPES ZOSTER				
alternative dictionary used: MedDRA 23.1				
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
HUMAN HERPESVIRUS 6 INFECTION REACTIVATION				
alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINE INFECTION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORAL CANDIDIASIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUCORMYCOSIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOCOCCAL SEPSIS			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	7 / 277 (2.53%)	4 / 279 (1.43%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA BACTERIAL			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

PNEUMONIA KLEBSIELLA alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 277 (0.00%) 0 / 0 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 0		
PNEUMONIA PARAINFLUENZAE VIRAL alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 277 (0.36%) 0 / 1 0 / 0	0 / 279 (0.00%) 0 / 0 0 / 0		
PNEUMONIA STAPHYLOCOCCAL alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 277 (0.00%) 0 / 0 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 1		
PROTEUS INFECTION alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 277 (0.36%) 0 / 1 0 / 0	0 / 279 (0.00%) 0 / 0 0 / 0		
SEPSIS alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	8 / 277 (2.89%) 0 / 8 0 / 3	11 / 279 (3.94%) 0 / 11 0 / 2		
SEPTIC EMBOLUS alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 277 (0.00%) 0 / 0 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 1		
SEPTIC SHOCK alternative dictionary used: MedDRA 23.1				

subjects affected / exposed	6 / 277 (2.17%)	8 / 279 (2.87%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 3	0 / 3	
STAPHYLOCOCCAL BACTERAEMIA alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL INFECTION alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	3 / 277 (1.08%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL SEPSIS alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STREPTOCOCCAL BACTERAEMIA alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STREPTOCOCCAL SEPSIS alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYSTEMIC CANDIDA alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

SYSTEMIC MYCOSIS alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 277 (0.00%) 0 / 0 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 0	
TOXOPLASMOSIS alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 277 (0.00%) 0 / 0 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 0	
URINARY TRACT INFECTION alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 277 (0.36%) 0 / 1 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 0	
UROSEPSIS alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 277 (0.00%) 0 / 0 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 0	
VASCULAR DEVICE INFECTION alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 277 (0.00%) 0 / 0 0 / 0	1 / 279 (0.36%) 0 / 1 0 / 0	
VIRAL INFECTION alternative dictionary used: MedDRA 23.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 277 (0.36%) 0 / 1 0 / 0	0 / 279 (0.00%) 0 / 0 0 / 0	
Metabolism and nutrition disorders DECREASED APPETITE alternative dictionary used: MedDRA 23.1			

subjects affected / exposed	1 / 277 (0.36%)	4 / 279 (1.43%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLUID RETENTION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERGLYCAEMIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERNATRAEMIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOKALAEMIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPONATRAEMIA			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALNUTRITION			
alternative dictionary used: MedDRA 23.1			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

METABOLIC ACIDOSIS alternative dictionary used: MedDRA 23.1 subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUMOUR LYSIS SYNDROME alternative dictionary used: MedDRA 23.1 subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	PAT arm	EAT arm	
Total subjects affected by non-serious adverse events subjects affected / exposed	271 / 277 (97.83%)	277 / 279 (99.28%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps) AML PROGRESSION alternative dictionary used: CTCAE 4.0 subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
DISEASE PROGRESSION AML alternative dictionary used: CTCAE 4.0 subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
LEUKEMIA CUTIS alternative dictionary used: CTCAE 4.0 subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
LOCALIZED LIVER RELAPSE OF LEUKEMIA alternative dictionary used: CTCAE 4.0 subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
RECURRENT AML			

alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
REFRACTORY AML			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences (all)	0	4	
Vascular disorders			
CAPILLARY LEAK SYNDROME			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences (all)	1	1	
FLUSHING			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)	
occurrences (all)	4	1	
HEMATOMA			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	13 / 277 (4.69%)	19 / 279 (6.81%)	
occurrences (all)	13	21	
HEMORRHAGE (MOUTH, NOSE AND CUTANEOUS)			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	2	
HOT FLASHES			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	2 / 279 (0.72%)	
occurrences (all)	2	2	
HYPERTENSION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	27 / 277 (9.75%)	26 / 279 (9.32%)	
occurrences (all)	37	33	
HYPOTENSION			
alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	20 / 277 (7.22%)	23 / 279 (8.24%)
occurrences (all)	23	28
INCREASED COAGULATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
LYMPHEDEMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
ORTHOSTATISM		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PETECHIAE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PHLEBITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	12 / 277 (4.33%)	12 / 279 (4.30%)
occurrences (all)	12	12
PSEUDOANEURYSM		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RIGHT SUPERFICIAL MIDDLE CEREVRAL ARTERY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
THROMBOEMBOLIC EVENT		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	7 / 277 (2.53%)	12 / 279 (4.30%)
occurrences (all)	8	13

<p>VASCULITIS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>7 / 277 (2.53%)</p> <p>8</p>	<p>9 / 279 (3.23%)</p> <p>14</p>	
<p>VENO OCCLUSIVE DISEASE</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 277 (0.00%)</p> <p>0</p>	<p>1 / 279 (0.36%)</p> <p>1</p>	
<p>General disorders and administration site conditions</p> <p>ALTERATION OF GENERAL STATUS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>CHILLS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>CHEST PAIN</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>DEATH NOS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>DISCOMFORT</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>EDEMA FACE</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>EDEMA HANDS</p> <p>alternative dictionary used: CTCAE</p>	<p>0 / 277 (0.00%)</p> <p>0</p> <p>39 / 277 (14.08%)</p> <p>41</p> <p>0 / 277 (0.00%)</p> <p>0</p> <p>1 / 277 (0.36%)</p> <p>1</p> <p>0 / 277 (0.00%)</p> <p>1</p> <p>5 / 277 (1.81%)</p> <p>5</p>	<p>1 / 279 (0.36%)</p> <p>1</p> <p>41 / 279 (14.70%)</p> <p>42</p> <p>1 / 279 (0.36%)</p> <p>0</p> <p>1 / 279 (0.36%)</p> <p>7 / 279 (2.51%)</p> <p>7</p>	

4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DRY COUGH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
EDEMA LEG		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
EPIGASTRIC PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
EDEMA LIMBS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	29 / 277 (10.47%)	29 / 279 (10.39%)
occurrences (all)	42	36
FATIGUE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	76 / 277 (27.44%)	78 / 279 (27.96%)
occurrences (all)	99	98
FACIAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)
occurrences (all)	2	0
FEVER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	30 / 277 (10.83%)	34 / 279 (12.19%)
occurrences (all)	41	44
FLU LIKE SYMPTOMS		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
FLUID RETENTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GASTRIC PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GENERAL EDEMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GENERALIZED EDEMA (GRAFT SYNDROM)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HAND PAIN (LEFT)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HYDROPS WITH HYPOALBUMINEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HYPERTHERMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
IATROGENIC FLUID RETENTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

INFUSE RELATED REACTION (AFTER PLATELET alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	0 / 279 (0.00%) 0
INFUSION RELATED REACTION alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	1 / 279 (0.36%) 1
INFUSION SITE EXTRAVASATION alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 2	0 / 279 (0.00%) 0
INJECTION SITE REACTION alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	18 / 277 (6.50%) 19	17 / 279 (6.09%) 17
LEGS EDEMA alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	0 / 279 (0.00%) 0
LOCALIZED EDEMA alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	12 / 277 (4.33%) 12	18 / 279 (6.45%) 19
MALAISE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	4 / 277 (1.44%) 4	5 / 279 (1.79%) 5
MULTI-ORGAN FAILURE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	6 / 277 (2.17%) 6	7 / 279 (2.51%) 11
NECK EDEMA alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
NESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
NIGHT SWEATS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	2 / 279 (0.72%)
occurrences (all)	2	2
NIGHT SWEETING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NON-CARDIAC CHEST PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	19 / 277 (6.86%)	11 / 279 (3.94%)
occurrences (all)	19	18
PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	11 / 277 (3.97%)	12 / 279 (4.30%)
occurrences (all)	13	14
PAIN AROUND GROIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
PAIN AT SITE OF IMPLANTABLE VENOUS ACCES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAIN AT PORT-A-CATH RESERVOIR SITE		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAIN HAND/LOWER LIMBS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PAIN CATHETER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
PAIN HIPS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PAIN KNEES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SHOULDER PAIN (LEFT)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RETROSTERNAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
UNSPECIFIED CHEST PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
WORSENING GENERAL CONDITION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

Immune system disorders			
ACUTE GRAFT VERSUS HOST DISEASE (CUTANEO			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
AGVHD			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
ALLERGIC REACTION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	22 / 277 (7.94%)	16 / 279 (5.73%)	
occurrences (all)	23	18	
ANAPHYLAXIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)	
occurrences (all)	2	0	
CUTANEOUS AND DIGESTIVE GVHD			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)	
occurrences (all)	3	0	
CUTANEOUS GVH DISEASE			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
CUTANEOUS GVHD			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
DIGESTIVE GVHD			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
GVHD			
alternative dictionary used: CTCAE			

4.0			
subjects affected / exposed	0 / 277 (0.00%)	3 / 279 (1.08%)	
occurrences (all)	0	4	
GVHD (INTESTINE)			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
GVHD CUTANEOUS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
GVHD OF THE SKIN			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	2	0	
GVHD SKIN			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
IMMUNE RECONSTITUTION INFLAMMATORY SYNDR			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
SKIN GVHD			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)	
occurrences (all)	2	3	
Reproductive system and breast disorders			
VAGINAL ATROPHY			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
BALANITIS			
alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BREAK THROUGH BLEEDING (DURING LYNESTERO alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BREAST PAIN alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BREAST TENDERNESS (SINCE CONTRACEPTION C alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
EPISTAXIS alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HEMORRHAGIC LESION MEATUS URETHRAE alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INFLAMMATION LABIA alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
MENORRHAGIA alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
METRORRHAGIA alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PELVIC PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
PENILE PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PENIS ULCER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PERINEAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PROSTATIC OBSTRUCTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PROSTATISM		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
TESTICULAR DISORDER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
TESTICULAR PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1

<p>UTERINE HEMORRHAGE</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>VAGINAL DISCHARGE</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>VAGINAL HEMORRHAGE</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>VAGINAL PAIN</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>			
	0 / 277 (0.00%)	3 / 279 (1.08%)	
	0	3	
	1 / 277 (0.36%)	0 / 279 (0.00%)	
	1	0	
	5 / 277 (1.81%)	5 / 279 (1.79%)	
	7	5	
	0 / 277 (0.00%)	1 / 279 (0.36%)	
	0	1	
<p>Respiratory, thoracic and mediastinal disorders</p> <p>ADULT RESPIRATORY DISTRESS SYNDROME</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ALLERGIC RHINITIS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ASTHMA</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ATELECTASIS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>BIBASAL CREPITATIONS</p>			
	4 / 277 (1.44%)	7 / 279 (2.51%)	
	4	9	
	1 / 277 (0.36%)	1 / 279 (0.36%)	
	1	1	
	0 / 277 (0.00%)	1 / 279 (0.36%)	
	0	1	
	0 / 277 (0.00%)	1 / 279 (0.36%)	
	0	1	

alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BIBASAL CREPITUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BI-BASAL CREPITUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BILATERAL NASAL OBSTRUCTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOODY SPUTUM		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BRONCHIAL OBSTRUCTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BRONCHOPULMONARY HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	3 / 279 (1.08%)
occurrences (all)	0	3
BRONCHOSPASM		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CHEST PAIN		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CHOKING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
COMMON COLD		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
COPD EXACERBATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
COUGH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	64 / 277 (23.10%)	66 / 279 (23.66%)
occurrences (all)	76	77
DESATURATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
DIFFICULT WEANING FROM MECHANICAL VENTIL		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
DRY NOSE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DRY THROAT		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

DYSYPNEA			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	53 / 277 (19.13%)	56 / 279 (20.07%)	
occurrences (all)	65	72	
EPISTAXIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	29 / 277 (10.47%)	33 / 279 (11.83%)	
occurrences (all)	33	39	
EPISTASIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
HEMOPTYSIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)	
occurrences (all)	2	3	
HICCUPS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	3 / 277 (1.08%)	0 / 279 (0.00%)	
occurrences (all)	3	0	
HOARSENESS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
HYPERVENTILATING			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
HYPERVENTILATION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
HYPERVENTILLATION			
alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HYPOXIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	8 / 277 (2.89%)	6 / 279 (2.15%)
occurrences (all)	11	6
LARYNGEAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
LARYNGEAL INFLAMMATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
LUNG INFILTRATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
NASAL CONGESTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	7 / 279 (2.51%)
occurrences (all)	1	7
NASAL DISCHARGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NASAL DRIP		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NON-SPECIFIC INTERSTITIAL PNEUMONIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

NOSE PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PHARYNGOLARYNGEAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
PHARYNX PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
PLEURAL EFFUSION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	13 / 279 (4.66%)
occurrences (all)	4	14
PLEURAL INFLAMMATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PLEURAL RUB		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PLEURITIC PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	3 / 279 (1.08%)
occurrences (all)	3	4
PNEUMONITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	4 / 279 (1.43%)
occurrences (all)	4	4
PNEUMOPATHY		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
PNEUMOTHORAX		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
PRODUCTIVE COUGH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	22 / 277 (7.94%)	23 / 279 (8.24%)
occurrences (all)	25	26
POSTNASAL DRIP		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PULMONARY EDEMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	4 / 279 (1.43%)
occurrences (all)	4	4
PULMONARY EMPHYSEMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PULMONARY HYPERTENSION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PULMONARY RALES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RALES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

RESPIRATORY FAILURE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	4 / 279 (1.43%)
occurrences (all)	5	7
RHINITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)
occurrences (all)	2	0
RETICULONODULAR PULMONARY SYNDROME		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RHONCHI (BOTH LUNGS LOWER FIELD)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
RHINORRHEA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	4 / 279 (1.43%)
occurrences (all)	1	4
RUNNY NOSE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SINUS DISORDER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
SORE THROAT		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	15 / 277 (5.42%)	15 / 279 (5.38%)
occurrences (all)	19	15
TACHYPNEA		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	5 / 277 (1.81%)	5 / 279 (1.79%)	
occurrences (all)	6	6	
THROAT PAIN			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)	
occurrences (all)	2	3	
WHEEZING			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	8 / 277 (2.89%)	9 / 279 (3.23%)	
occurrences (all)	8	9	
UNSPECIFIC PULMONARY INFILTRATES			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
AGITATION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	4 / 277 (1.44%)	5 / 279 (1.79%)	
occurrences (all)	5	6	
ANXIETY			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	33 / 277 (11.91%)	30 / 279 (10.75%)	
occurrences (all)	36	39	
ANXIODEPRESSION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
CONFUSION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	14 / 277 (5.05%)	15 / 279 (5.38%)	
occurrences (all)	16	15	
DELIRIUM			
alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	0 / 277 (0.00%)	3 / 279 (1.08%)
occurrences (all)	0	3
DEPRESSION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	9 / 277 (3.25%)	11 / 279 (3.94%)
occurrences (all)	13	13
HALLUCINATIONS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	4 / 279 (1.43%)
occurrences (all)	4	4
IDEOMATOR SLOWDOWN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INSOMNIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	34 / 277 (12.27%)	29 / 279 (10.39%)
occurrences (all)	42	32
NERVOUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PRESYNCOPE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
RESTLESSNESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	2
SUICIDAL IDEATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

VIVID DREAMS alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	0 / 279 (0.00%) 0	
WEAK, LITTLE RESPONSE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1	
Investigations ALKALINE PHOSPHATASE INCREASED alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) ASPARTATE AMINOTRANSFERASE INCREASED alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) BLOOD BILIRUBIN INCREASED alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) CREATININE INCREASED alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) CRP INCREASE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) CRP INCREASED alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) ELECTROCARDIOGRAM QT CORRECTED INTERVAL PROLONGED	1 / 277 (0.36%) 1 1 / 277 (0.36%) 1 1 / 277 (0.36%) 1 0 / 277 (0.00%) 0 2 / 277 (0.72%) 2	1 / 279 (0.36%) 1 0 / 279 (0.00%) 0 0 / 279 (0.00%) 0 3 / 279 (1.08%) 3 1 / 279 (0.36%) 1 1 / 279 (0.36%) 1	

alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	4 / 279 (1.43%)
occurrences (all)	1	4
GGT INCREASED		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	12 / 277 (4.33%)	14 / 279 (5.02%)
occurrences (all)	27	29
HEMOCULT CATHETER : STENOTROPHOMONAS MAL		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HYPOKALEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	4 / 279 (1.43%)
occurrences (all)	0	6
HYPOPHOSPHATEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
INCREASED CRP		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
INCREASED LDH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INCREASING C-REACTIVE PROTEIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
INCREASING CRP		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	2	0	
LACTATE DEHYDROGENASE INCREASED			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	2	0	
LDH INCREASED			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
NEUTROPHIL COUNT DECREASED			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
NOS PAIN RIGHT HYPOCHONDER			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
PLATELET COUNT DECREASED			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	3 / 277 (1.08%)	5 / 279 (1.79%)	
occurrences (all)	3	8	
WEIGHT GAIN			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)	
occurrences (all)	2	1	
WEIGHT LOSS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	5 / 279 (1.79%)	
occurrences (all)	1	5	
Injury, poisoning and procedural complications			
ABDOMINAL ABSCESS BLEEDING			
alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ANKLE FRACTURE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BRUISING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BURN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CENTRAL CATHETER VENOUS INJURY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
FALL		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	5 / 279 (1.79%)
occurrences (all)	3	5
FISSURE LEG		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
FRACTURE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
GASTROINTESTINAL STOMA NECROSIS		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
HEAD TRAUMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HEMORRHAGE (PERFUSION CATHETER)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INTESTINAL STOMA SITE BLEEDING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
MORPHINE INTOXICATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAIN AROUND PAC DEVICE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
POSTOPERATIVE HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PRESSURE ULCER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
TRANSFUSION REACTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

<p>WOUND COMPLICATION</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 277 (0.00%)</p> <p>0</p>	<p>1 / 279 (0.36%)</p> <p>1</p>	
<p>WOUND LEG</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 277 (0.00%)</p> <p>0</p>	<p>1 / 279 (0.36%)</p> <p>1</p>	
<p>WOUND NOSE</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 277 (0.36%)</p> <p>1</p>	<p>1 / 279 (0.36%)</p> <p>1</p>	
<p>WOUND NOSTRILS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 277 (0.36%)</p> <p>1</p>	<p>0 / 279 (0.00%)</p> <p>0</p>	
<p>Cardiac disorders</p> <p>ACUTE CORONARY SYNDROME</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ATRIAL ARRHYTHMIA</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ATRIAL FIBRILLATION</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ATRIAL FLUTTER</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ATRIAL TACHYCARDIA</p> <p>alternative dictionary used: CTCAE 4.0</p>	<p>1 / 277 (0.36%)</p> <p>1</p> <p>1 / 277 (0.36%)</p> <p>1</p> <p>2 / 277 (0.72%)</p> <p>2</p> <p>1 / 277 (0.36%)</p> <p>1</p>	<p>0 / 279 (0.00%)</p> <p>0</p> <p>0 / 279 (0.00%)</p> <p>0</p> <p>6 / 279 (2.15%)</p> <p>6</p> <p>3 / 279 (1.08%)</p> <p>4</p>	

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ATRIOVENTRICULAR BLOCK		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
AV-NODAL RE-ENTRY TACHYCARDIA (AVNRT)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BRADYCARDIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	0 / 279 (0.00%)
occurrences (all)	3	0
CARDIAC ARREST		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)
occurrences (all)	1	2
CARDIOGENIC SHOCK		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	3	0
CARDIOPULMONARY FAILURE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CHEST TIGHTNESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CHEST PAIN - CARDIAC		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)
occurrences (all)	3	1

HEART MURMUR		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HEART FAILURE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	3 / 279 (1.08%)
occurrences (all)	5	3
MYOPERICARDITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
N-STEMI WITH ABNORMAL CARDIAC ENZYMES AN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PALPITATIONS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	3 / 279 (1.08%)
occurrences (all)	1	3
PERICARDIAL EFFUSION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	3 / 279 (1.08%)
occurrences (all)	0	3
SINUS BRADYCARDIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	11 / 277 (3.97%)	18 / 279 (6.45%)
occurrences (all)	13	19
SINUS TACHYCARDIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
TACHYCARDIA		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	14 / 277 (5.05%)	9 / 279 (3.23%)	
occurrences (all)	14	9	
SYSTOLIC MURMUR			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
TACHYCARDIA (DUE TO HYPOKALEMIA)			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
TACHYCARDIA (INTERMITTENT)			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
VENTRICULAR FIBRILLATION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences (all)	1	1	
Nervous system disorders			
AKATHISIA			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences (all)	1	1	
CONCUSSION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
CONFUSION (DUE TO MEDICATION)			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
DEPRESSED LEVEL OF CONSCIOUSNESS			
alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	4 / 277 (1.44%)	2 / 279 (0.72%)
occurrences (all)	4	2
DIZZINESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	10 / 277 (3.61%)	15 / 279 (5.38%)
occurrences (all)	10	16
DYSARTHRIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
DYSGEUSIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ENCEPHALOPATHY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	6
EXTRAPYRAMIDAL DISORDER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HEADACHE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	67 / 277 (24.19%)	65 / 279 (23.30%)
occurrences (all)	91	88
HEMIPARESIS (LEFT SIDE)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
HEMIPARESIS LEFT SIDE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

INSOMNIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
INTRACRANIAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)
occurrences (all)	4	1
LETHARGY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
LIGHT HEADED		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
MENINGISMUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
MERALGIA PARESTHETICA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
MOVEMENTS INVOLUNTARY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
MYOCLONIA IN THE UPPER LIMBS AND IN THE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
MYOCLONUS		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
NERVE PAIN FEET		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NEURALGIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
NEUROLOGICAL DETERIORATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ONE-SIDED FACIAL PARALYSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAINFUL AND TINGLING FEELING IN FINGER T		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PERIPHERAL SENSORY NEUROPATHY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PARESTHESIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	5 / 279 (1.79%)
occurrences (all)	3	5
POLYNEUROPATHY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

PRESYNCOPE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)
occurrences (all)	1	2
RESTLESS LEGS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
REVERSIBLE POSTERIOR LEUKOENCEPHALOPATHY SYNDROME		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SEIZURE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)
occurrences (all)	3	1
SOMNOLENCE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)
occurrences (all)	3	1
SINUS PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
STROKE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SUBARACHNOID HAEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
SYNCOPE		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	6 / 277 (2.17%)	5 / 279 (1.79%)	
occurrences (all)	6	6	
TINGLING FEET/LEGS AFTER EXERCISE			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
TRANSIENT ISCHEMIC ATTACKS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
TINGLING SENSATION (RIGHT HAND)			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
TREMOR			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	4 / 277 (1.44%)	1 / 279 (0.36%)	
occurrences (all)	4	1	
VASOVAGAL REACTION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	3 / 277 (1.08%)	2 / 279 (0.72%)	
occurrences (all)	3	2	
VESTIBULAR NEURITIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
ANEMIA			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	3 / 279 (1.08%)	
occurrences (all)	0	3	
BACTEREMIA ESCHERICHIA COLI			
alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BACTERIEMIA ESCHERICHIA COLI		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD BILIRUBIN INCREASED		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD BLISTER MOUTH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BONE MARROW HYPOCELLULAR		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	1
COAGULATION DISORDER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DISSEMINATED INTRAVASCULAR COAGULATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	3 / 279 (1.08%)
occurrences (all)	0	3
FEBRILE NEUTROPENIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	26 / 277 (9.39%)	18 / 279 (6.45%)
occurrences (all)	27	19
HEMORRHAGIC DIATHESIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

HYPERFERRITINEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
LEFT CERVICAL ADENOPATHY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
LEUKOCYTOSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
LYMPHADENOPATHY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PETECHIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PETECHIAE ON TONGUE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SPLEEN DISORDER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SPLENOMEGALY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)
occurrences (all)	2	0
THROMBOTIC ANGIOPATHY		
alternative dictionary used: CTCAE 4.0		

<p>subjects affected / exposed</p> <p>0 / 277 (0.00%)</p> <p>1 / 279 (0.36%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p>			
<p>THROMBOTIC THROMBOCYTOPENIC PURPURA</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>2 / 277 (0.72%)</p> <p>2 / 279 (0.72%)</p> <p>occurrences (all)</p> <p>2</p> <p>2</p>			
<p>Ear and labyrinth disorders</p> <p>EAR BLEEDING</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>1 / 277 (0.36%)</p> <p>0 / 279 (0.00%)</p> <p>occurrences (all)</p> <p>1</p> <p>0</p>			
<p>HEARING IMPAIRED</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>1 / 277 (0.36%)</p> <p>3 / 279 (1.08%)</p> <p>occurrences (all)</p> <p>1</p> <p>3</p>			
<p>EAR PAIN</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>4 / 277 (1.44%)</p> <p>5 / 279 (1.79%)</p> <p>occurrences (all)</p> <p>4</p> <p>5</p>			
<p>MIDDLE EAR INFLAMMATION</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>0 / 277 (0.00%)</p> <p>1 / 279 (0.36%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p>			
<p>VERTIGO</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>7 / 277 (2.53%)</p> <p>6 / 279 (2.15%)</p> <p>occurrences (all)</p> <p>7</p> <p>6</p>			
<p>Eye disorders</p> <p>- ITCHY EYES</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>0 / 277 (0.00%)</p> <p>1 / 279 (0.36%)</p> <p>occurrences (all)</p> <p>0</p> <p>1</p>			
<p>ANISOCORIA</p> <p>alternative dictionary used: CTCAE 4.0</p>			

subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
BLURRED VISION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	5 / 277 (1.81%)	4 / 279 (1.43%)
occurrences (all)	5	4
CATARACT		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CONJUNCTIVAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CONJUNCTIVITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	4 / 279 (1.43%)
occurrences (all)	4	4
DECREASED VISUAL ACUITY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
DACRYOCYSTITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
DIPLOPIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DRY EYE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	1 / 279 (0.36%)
occurrences (all)	4	1

EYE HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
EYE PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	4 / 279 (1.43%)
occurrences (all)	4	4
EYE HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	3 / 279 (1.08%)
occurrences (all)	0	3
FLOATERS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	1
HEMORRHAGE EYE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	3
FUNDUS HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
IRRITATION AT RIGHT EYE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HORDEOLUM (RIGHT EYELID)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
IRRITATION EYE		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
KERATITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
MACULAR HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NODULES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
OBSERVANCE OF YELLO LIGHT		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
OCULAR DIPLOPIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
OPTIC NERVE DISORDER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	4
PHOTOPHOBIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	5
RETINA BLEEDING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

RETINAL BLEEDING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RETINAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
SMALL BLEEDING IN RETINA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SUBCONJUNCTIVAL BLEEDING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SUB-CONJUNCTIVAL HAEMORRHAGE (LEFT)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SUBCONJUNCTIVAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SWOLLEN EYELIDS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
VISUAL DISTURBANCE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
VITREOUS HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
WATERING EYES			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
XEROPHTHALMIA			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
ABDOMINAL CRAMPS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL DISTENSION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences (all)	0	2	
ABDOMINAL PAIN			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	67 / 277 (24.19%)	71 / 279 (25.45%)	
occurrences (all)	87	82	
ANAL ABSCESS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
ANAL FISSURE			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)	
occurrences (all)	3	2	
ANAL FISTULA			
alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	6 / 277 (2.17%)	2 / 279 (0.72%)
occurrences (all)	7	3
ANAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)
occurrences (all)	1	2
ANAL MUCOSITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
ANAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	11 / 277 (3.97%)	15 / 279 (5.38%)
occurrences (all)	11	22
ANAL ULCER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
APHT		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
APHTHOUS STOMATITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
APHTOSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
APHTS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

ASCITES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
APTHS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOATING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD IN STOOL		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BELCHING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
CHEILITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
COLITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	13 / 277 (4.69%)	6 / 279 (2.15%)
occurrences (all)	14	7
CONSTIPATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	57 / 277 (20.58%)	54 / 279 (19.35%)
occurrences (all)	67	62
COLONIC PERFORATION		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DENTAL SNAGS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DENTAL CARIES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	1
DENUTRITION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DIARRHEA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	105 / 277 (37.91%)	98 / 279 (35.13%)
occurrences (all)	149	156
DIVERTICULOSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DOUGLAS ABCESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
DRY LIPS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
DRY MOUTH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	11 / 277 (3.97%)	6 / 279 (2.15%)
occurrences (all)	11	6

DYSGEUSIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
DYSPEPSIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	1
DUODENAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
DYSPHAGIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	7 / 277 (2.53%)	3 / 279 (1.08%)
occurrences (all)	8	3
ENTERITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ENTEROCOLITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	3
EPIGASTRALGIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
EPIGASTRIC PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	3 / 279 (1.08%)
occurrences (all)	1	3
ESOPHAGITIS		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	5 / 277 (1.81%)	5 / 279 (1.79%)
occurrences (all)	6	5
GASTRIC HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
FLATULENCE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GASTRIC PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GASTRITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)
occurrences (all)	3	1
GASTROESOPHAGEAL REFLUX DISEASE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	6 / 279 (2.15%)
occurrences (all)	1	6
GASTROINTESTINAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	3 / 279 (1.08%)
occurrences (all)	4	3
GASTROPARESIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GINGIVAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	2 / 279 (0.72%)
occurrences (all)	3	2

GINGIVAL HYPERTROPHIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
GINGIVAL INFLAMMATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GINGIVAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	4 / 279 (1.43%)
occurrences (all)	3	4
GINGIVAL ULCER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GINGIVITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GINVIVAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
GUM HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HEARTBURN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
HEMATEMESIS		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HEMORRHOIDAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
HEMORRHOIDS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	13 / 277 (4.69%)	16 / 279 (5.73%)
occurrences (all)	17	21
ILEAL OBSTRUCTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ILEITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ILEITUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ILEUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INFLAMMATION TEETH LOVER RIGHT JAW		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
INTESTINAL MUCOSITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

INTESTINAL OBSTRUCTION alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)			1 / 277 (0.36%) 1	0 / 279 (0.00%) 0
JEJUNITIS alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)			0 / 277 (0.00%) 0	1 / 279 (0.36%) 1
LACK OF APPETITE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)			0 / 277 (0.00%) 0	1 / 279 (0.36%) 1
LOSS OF APPETITE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)			0 / 277 (0.00%) 0	1 / 279 (0.36%) 1
LOWER GASTROINTESTINAL HEMORRHAGE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)			0 / 277 (0.00%) 0	3 / 279 (1.08%) 3
MELENA alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)			1 / 277 (0.36%) 1	2 / 279 (0.72%) 2
MESENTERIC ISCHEMIA alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)			0 / 277 (0.00%) 0	1 / 279 (0.36%) 1
MOUTH APHTE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)			0 / 277 (0.00%) 0	1 / 279 (0.36%) 1
MOUTH ULCER alternative dictionary used: CTCAE 4.0				

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
MUCOSITIS (ILEUM AND COLON)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
MUCOSITIS ORAL		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	91 / 277 (32.85%)	75 / 279 (26.88%)
occurrences (all)	127	109
NAUSEA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	77 / 277 (27.80%)	77 / 279 (27.60%)
occurrences (all)	105	103
ORAL DYSESTHESIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
ORAL HEMORRHAGE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	8 / 277 (2.89%)	3 / 279 (1.08%)
occurrences (all)	8	3
ORAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	3
PANCOLITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
PANCREATITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2

PAROTIC GLAND PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PAROTIDITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	4	0
PAROTITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PERIANAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PERICORONITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PERIODONTAL DISEASE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
PETECHIAE MOUTH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SACRO GLUTEAL ABSCESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PYROSIS		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SMALL INTESTINAL MUCOSITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	5
SIALADENITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SORE THROAT		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SPLENOMEGALY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
STOMACH PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
STOMATITIS APHTHOSA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
THIRST		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
STOMATITIS APHTOSA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

<p>TOOTHACHE</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>8 / 277 (2.89%)</p> <p>8</p>	<p>5 / 279 (1.79%)</p> <p>5</p>	
<p>UPPER GI TRACT GVHD</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 277 (0.00%)</p> <p>0</p>	<p>1 / 279 (0.36%)</p> <p>1</p>	
<p>TYPHLITIS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 277 (1.08%)</p> <p>3</p>	<p>3 / 279 (1.08%)</p> <p>3</p>	
<p>VOMITING</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>62 / 277 (22.38%)</p> <p>83</p>	<p>50 / 279 (17.92%)</p> <p>62</p>	
<p>WOUND MOUTH MUCOSA</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 277 (0.00%)</p> <p>0</p>	<p>1 / 279 (0.36%)</p> <p>1</p>	
<p>Hepatobiliary disorders</p> <p>ACUTE GRAFT VERSUS HOST DISEASE</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ACUTE HEPATIC CYTOLYSIS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>CHOLANGITIS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>CHOLECYSTITIS</p> <p>alternative dictionary used: CTCAE</p>	<p>1 / 277 (0.36%)</p> <p>1</p> <p>1 / 277 (0.36%)</p> <p>1</p> <p>1 / 277 (0.36%)</p> <p>1</p>	<p>0 / 279 (0.00%)</p> <p>0</p> <p>0 / 279 (0.00%)</p> <p>0</p> <p>0 / 279 (0.00%)</p> <p>0</p>	

4.0		
subjects affected / exposed	3 / 277 (1.08%)	0 / 279 (0.00%)
occurrences (all)	5	0
CHOLESTASIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CYTOLYTIC HEPATITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
CYTOLYSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DRUG INDUCED HEPATITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GALLBLADDER LITHIASIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HEPATIC CHOLESTASIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
HEPATIC CYTOLYSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HEPATIC FAILURE		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)
occurrences (all)	2	0
HEPATIC CYTOLYSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	5 / 277 (1.81%)	3 / 279 (1.08%)
occurrences (all)	6	5
HEPATIC INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HEPATIC LESION UNKNOWN ORIGIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
HEPATOMEGALY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INCREASE IN LIVER ENZYMES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INCREASED LIVER FUNCTION TESTS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ISCHEMIC HEPATITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
JAUNDICE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

LIVER TOXICITY alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1	
STEATOSIS HEPATIS alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	0 / 279 (0.00%) 0	
VENO-OCCLUSIVE DISEASE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	0 / 279 (0.00%) 0	
VENOOCCLUSIVE LIVER DISEASE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	1 / 279 (0.36%) 1	
Skin and subcutaneous tissue disorders ACUTE CUTANEOUS GVH DISEASE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) ACUTE FEBRILE NEUTROPHILIC DERMATOSIS alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) ACUTE GVH DISEASE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) BACK FOLLICULITIS alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all) BULLOUS DERMATITIS alternative dictionary used: CTCAE	1 / 277 (0.36%) 1 1 / 277 (0.36%) 3 0 / 277 (0.00%) 0 0 / 277 (0.00%) 0	0 / 279 (0.00%) 0 0 / 279 (0.00%) 0 1 / 279 (0.36%) 1 1 / 279 (0.36%) 1	

4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	2	1
CELLULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	3 / 279 (1.08%)
occurrences (all)	1	3
BLISTER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CELLULITUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CRUSTS (LEFT THIGH)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CRUSTS (SCALP AND LEFT THIGH)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CUTANEOS GVH DISEASE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CUTANEOUS GVHD		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CUTANEUS NODES		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CYTOSAR RASH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DESQUAMATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DRY SKIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	5 / 277 (1.81%)	10 / 279 (3.58%)
occurrences (all)	5	10
ECCHYMOSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ECZEMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ECZEMA CRAQUELÉ		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ECZEMA FACE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ECZEMA LEFT CHEST		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

ECZEMA RASH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
ERYTHEMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	5 / 279 (1.79%)
occurrences (all)	3	5
ERYTHEMA (LEG)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ERYTHEMA AROUND NAIL		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ERYTHEMA CHEST AND CERVICAL AND LOWER LE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ERYTHEMA MULTIFORME		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	8 / 277 (2.89%)	5 / 279 (1.79%)
occurrences (all)	9	5
ERYTHEMATOUS PURPLISH LESION (ON BACK AN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
ERYTHEMATOUS RASH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	3	0
ERYTHRODERMA		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)
occurrences (all)	3	1
EXANTHEMA BOTH LEGS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
FACIAL RASH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
FOLLICULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	2 / 279 (0.72%)
occurrences (all)	5	2
FOLLICULITIS (ABDOMEN)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
FOLLICULITIS (BOTH ARMPITS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
FOLLICULITIS EAR		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HAND FOOT MOUTH DISEASE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
HERPES LABIALIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

HERPES NASALIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HERPES SIMPLEX		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HYDRADENITIS (BOTH ARMPITS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HYPERHIDROSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	3 / 279 (1.08%)
occurrences (all)	1	3
HYPODERMITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HYPOHIDROSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	4 / 279 (1.43%)
occurrences (all)	4	4
INDURATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INGROWN NAIL		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
INTERTRIGO INGUINAL		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
LIGHT PETECHIAE ON ALL BODY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NAIL BLEEDING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NAIL DISCOLORATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NIGHT SWEATS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	3
NOCTURNAL SWEATS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NODULUS RIGHT UPPER LEG (ECZEMA)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
OCCURENCE OF A SUBCUTANEOUS NODULE IN RI		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
OTHER CUTANEOUS NODES		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	20 / 277 (7.22%)	9 / 279 (3.23%)
occurrences (all)	25	11
PANNICULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PECTORAL ECZEMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PERIORBITAL EDEMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PETECHIA (INFERIOR LIMBS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PETECHIAE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	6 / 279 (2.15%)
occurrences (all)	4	6
PETECHIAE ARMS AND LEGS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PETECHIAL BLEEDING SIGNS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

PETECHIAL RASH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PETECHIEAE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PRURITUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	31 / 277 (11.19%)	36 / 279 (12.90%)
occurrences (all)	33	42
PSORIASIS INVERSA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PURPURA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	7 / 277 (2.53%)	4 / 279 (1.43%)
occurrences (all)	7	7
PURPURA (RIGHT ARM)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
R FOLLICULITUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RASH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	6 / 277 (2.17%)	3 / 279 (1.08%)
occurrences (all)	7	4
RASH (DUE TO CYTARABINE)		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
RASH (NO FURTHER INFORMATION)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RASH (SMALL PUSTULE AND INFLAMMATION)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RASH FACE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
RASH MACULO-PAPULAR		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	74 / 277 (26.71%)	56 / 279 (20.07%)
occurrences (all)	85	69
REDNESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
REDNESS FACE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SCALP PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SCALP RASH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

SCRAPING SENSATION ALL OVER THE BODY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SEBORRHEIC KERATOSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SINUS PILONIDALIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	3
SKIN AE BECAUSE PROVEN CUTANEOUS ASPERGI		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS - OTHER, SP		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SKIN DESQUAMATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	3 / 279 (1.08%)
occurrences (all)	0	3
SKIN HYPERPIGMENTATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SKIN INDURATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SKIN INFECTION (DERMATOMYCOSIS)		

alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SKIN INFECTION (PERINEAL CELLULITIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SKIN INFLAMMATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SKIN LESIONS ARMS AND LEGS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
SKIN RASH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SKIN REDNESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SKIN ULCERATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	20 / 277 (7.22%)	14 / 279 (5.02%)
occurrences (all)	23	17
SUBCUTANEOUS TISSUE DISORDER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SWEATING		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SWEET SYNDROME		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
SWOLLEN TOE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
TELANGIECTASIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
TOXIDERMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
URTICARIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	5 / 277 (1.81%)	1 / 279 (0.36%)
occurrences (all)	5	1
VASCULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
VESICULAR LESION LEFT THORACAL		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
VESICULAR RASH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

WHITLOW alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1	
Renal and urinary disorders ACUTE KIDNEY INJURY alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	13 / 277 (4.69%) 15	7 / 279 (2.51%) 9	
ACUTE RENAL FAILURE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	2 / 279 (0.72%) 2	
ACUTE URETHRITIS alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1	
BLADDER PAIN alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	0 / 279 (0.00%) 0	
BLADDER SPASM alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1	
CHRONIC KIDNEY DISEASE alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1	
CYSTITIS alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1	
CYSTITIS NONINFECTIVE alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GLOMERULONEPHRITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DYSURIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
KIDNEY DYSFUNCTION (WORSENING)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
HEMATURIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	12 / 277 (4.33%)	17 / 279 (6.09%)
occurrences (all)	16	19
NOCTURIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
PAIN DURING URINATING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAIN ON PALPATION OF KIDNEYS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAINFUL URINATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

POLYDIPSIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PROTEINURIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RENAL FAILURE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	2 / 279 (0.72%)
occurrences (all)	2	2
PYELONEPHRITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RENAL FAILURE (DUE TO CICLOSPORINE)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
RENAL INSUFFICIENCY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	1
SCROTAL EDEMA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
URINARY FREQUENCY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	8 / 277 (2.89%)	12 / 279 (4.30%)
occurrences (all)	8	12
URINARY INCONTINENCE		
alternative dictionary used: CTCAE 4.0		

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>URINARY RETENTION</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>URINARY TRACT INFECTION</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>URINARY TRACT PAIN</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 277 (0.72%)</p> <p>2</p> <p>1 / 277 (0.36%)</p> <p>1</p> <p>0 / 277 (0.00%)</p> <p>0</p> <p>2 / 277 (0.72%)</p> <p>2</p>	<p>1 / 279 (0.36%)</p> <p>1</p> <p>2 / 279 (0.72%)</p> <p>2</p> <p>1 / 279 (0.36%)</p> <p>1</p> <p>4 / 279 (1.43%)</p> <p>4</p>	
<p>Endocrine disorders</p> <p>ENDOCRINE DISORDERS - OTHER, SPECIFY</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ADRENAL INSUFFICIENCY</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>HYPOPARATHYROIDISM</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 277 (0.00%)</p> <p>0</p> <p>1 / 277 (0.36%)</p> <p>1</p> <p>1 / 277 (0.36%)</p> <p>1</p> <p>1 / 277 (0.36%)</p> <p>1</p>	<p>1 / 279 (0.36%)</p> <p>1</p> <p>1 / 279 (0.36%)</p> <p>1</p> <p>0 / 279 (0.00%)</p> <p>0</p>	
<p>Musculoskeletal and connective tissue disorders</p> <p>ACHILLES STIFFNESS</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ARTHRALGIA</p> <p>alternative dictionary used: CTCAE 4.0</p>	<p>1 / 277 (0.36%)</p> <p>1</p>	<p>0 / 279 (0.00%)</p> <p>0</p>	

subjects affected / exposed	10 / 277 (3.61%)	17 / 279 (6.09%)
occurrences (all)	12	22
ARTHRITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	6 / 279 (2.15%)
occurrences (all)	4	6
BACK PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	18 / 277 (6.50%)	26 / 279 (9.32%)
occurrences (all)	18	29
BILATERAL ANAESTHESIA OF HANDS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BONE PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	16 / 277 (5.78%)	18 / 279 (6.45%)
occurrences (all)	18	21
CALF PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CERVICAL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CHEST WALL PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CRAMPS LEFT LEG		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

DECUBITUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
FEET CRAMP		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
FLANK PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)
occurrences (all)	1	2
GENERALIZED MUSCLE WEAKNESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	3
GENERALIZED PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GOUT		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
GOUT CRISIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GOUT CRISIS AT LEFT TIP TOES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GROIN PAIN		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HAND PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
HIP PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
HYPODERMITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INTERSCALARIC PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
JAW PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
JOINT EFFUSION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
JOINT INFLAMMATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
KNEE SWELLING		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	3	0

LEG ABSCESS (RIGHT) alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1
LEG ABSCESS (RIGHT) alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1
LEG CRAMPS alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	1 / 279 (0.36%) 1
LEG CRAMPS INTERMITTENT alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	0 / 277 (0.00%) 0	1 / 279 (0.36%) 1
LEG PAIN alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	1 / 279 (0.36%) 1
LUMBAR PAIN alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	0 / 279 (0.00%) 0
MUSCLE CRAMPS alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	0 / 279 (0.00%) 0
MUSCLE WEAKNESS LOWER LIMB alternative dictionary used: CTCAE 4.0 subjects affected / exposed occurrences (all)	1 / 277 (0.36%) 1	0 / 279 (0.00%) 0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DI alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
MYALGIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	19 / 277 (6.86%)	18 / 279 (6.45%)
occurrences (all)	20	21
MYOCLONIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
MYOSITIS (CALF)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NECK PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	9 / 277 (3.25%)	6 / 279 (2.15%)
occurrences (all)	9	6
PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PAIN ANKLE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAIN AT FEET		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PAIN BETWEEN SHOULDER BLADES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

PAIN CLAVICLE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PAIN FEET		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAIN HIP		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PAIN IN EXTREMITY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	3
PAIN LEGS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PAIN LEGS UNSPECIFIED		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAIN LIMBS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PAIN OF RIGHT HAUNCH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
POLYTENDINITIS		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
RIB CAGE PAIN (RIGHT)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SHOULDER PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SHOULDER PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
SHOULDER PAIN (RIGHT)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SUBCUTANEOUS NODULES		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
TENOSYNOVITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
TRISMUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
WRIST PAIN		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

Infections and infestations			
ABDOMINAL INFECTION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)	
occurrences (all)	1	2	
ALVEOLITIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
ANAL INFECTION (ENTEROCOCCUS FAECALIS)			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
ANORECTAL INFECTION			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	5 / 279 (1.79%)	
occurrences (all)	2	5	
APHT			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)	
occurrences (all)	2	1	
APPENDICITIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences (all)	0	2	
AXILLARY FOLLICULITIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
AXILLIARY GLAND INFECTION (HIDRADENITIS)			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)	
occurrences (all)	0	1	
BACTEREMIA			

alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	6 / 277 (2.17%)	4 / 279 (1.43%)
occurrences (all)	6	5
BACTEREMIA (HEMOCULTURE POSITIVE: ESCHE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BACTEREMIA (CORYNEBACTERIUM SPP.)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BACTEREMIA (E. COLI)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BACTEREMIA (ENTEROCOCCUS DOCUMENTATION)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BACTEREMIA (ENTEROCOCCUS FAECALIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BACTEREMIA (ENTEROCOCCUS FAECIUM)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	2
BACTEREMIA (ENTEROCOCCUS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BACTEREMIA (ESCHERICHIA COLI)		

alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BACTEREMIA (ESCHERICIA COLI)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BACTEREMIA (MRSA)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BACTEREMIA (PROTEUS MIRABILIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BACTEREMIA (PSEUDOMONAS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BACTEREMIA (S. HAEMOLYTICUS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BACTEREMIA (STAPHYLOCOCCUS EPIDERMIDIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
BACTEREMIA (STAPHYLOCOCCUS EPIDERMITIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
BACTEREMIA (STAPHYLOCOCCUS HEMOLITICUS)		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BACTEREMIA (STAPHYLOCOCCUS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BACTEREMIA (STREPTOCOCCUS MITIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BACTEREMIA E. FAECIUM/STAPHYLOCOCCUS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BACTERIEMA [TO STAPHYLOCOCCUS HAEMOLYTIC		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BACTERIEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLADDER INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
BLOOD		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD (ENTEROBACTER AEROGENES)		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD (ENTEROBACTER)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD (ENTEROCOCCUS FAECALIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD INFCETION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD INFECTION (CLOSTRIDIUM TERTIUM)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD INFECTION (CMV)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD INFECTION (CORYNEBACTERIUM)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD INFECTION (ENTEROCOCCUS FAECALIS S		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD INFECTION (ESCHERICHIA COLI)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD INFECTION (GEOTRICHUM CAPITUM)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD INFECTION (HHV-6)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD INFECTION (PROTEUS MIRABILIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
BLOOD INFECTION (STAPHYLOCOCCUS EPIDERMIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	2 / 279 (0.72%)
occurrences (all)	4	3
BLOOD INFECTION (STAPHYLOCOCCUS HAEMOLYTICUS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BLOOD INFECTION (STAPHYLOCOCCUS HEMOLYTICUS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
BLOOD INFECTION (STAPHYLOCOCCUS)		

alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)
occurrences (all)	2	0
BLOOD INFECTION (STREPTOCOCCUS MILLERI A)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD INFECTION (STREPTOCOCCUS MITS, STR)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD INFECTION (STREPTOCOCCUS PNEUMONIA)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BLOOD STREAM INFECTION (STAPH EPIDERMIDI)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
BONE INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
BRONCHIAL INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)
occurrences (all)	1	2
C.KRUSEI		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CANDIDAS KRUSEI IN BLOOD		
alternative dictionary used: CTCAE		

4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
CATHETER RELATED INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	15 / 277 (5.42%)	13 / 279 (4.66%)
occurrences (all)	15	14
CELLULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)
occurrences (all)	6	0
CENTRAL NERVOUS SYSTEM INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CEREBRAL ABCESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CEREBRAL ABSCESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CMV		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CMV BLOOD INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CMV INFECTION		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	2 / 277 (0.72%)	2 / 279 (0.72%)
occurrences (all)	2	2
CMV REACTIVATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	2	3
COLON DIVERTICULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
COLON INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	2 / 279 (0.72%)
occurrences (all)	1	2
CONJUNCTIVITIS INFECTIVE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CYTOMEGALOVIRUS PCR +		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
CYTOMEGALOVIRUS REACTIVATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
DACRYOCYSTITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
DIGESTIVE INFECTION (CANDIDA GUILLERMOND)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

DIGESTIVE TRACT INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
EBV REACTIVATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
ENCEPHALITIS INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)
occurrences (all)	0	3
ENDOCARDITIS INFECTIVE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ENTEROCOCCUS FAECIUM IN STOOL		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ENTEROCOLITIS INFECTIOUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	5 / 279 (1.79%)
occurrences (all)	6	5
EPSTEIN-BARR VIRUS INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ESOPHAGEAL CANDIDIASIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ESOPHAGEAL INFECTION		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
EYE INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)
occurrences (all)	2	0
FEBRILE SYNDROME		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
FOLLICULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	3 / 279 (1.08%)
occurrences (all)	0	3
FOLLICULITIS (STAPHYLOCOCCUS AUREUS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
FUSAOBACTERIUM NUCLATUM IN BLOOD		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
GALLBLADDER INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GASTROENTERITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
GASTROENTERITIS (VIRAL)		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
GASTROENTERITIS INFECTIOUS (NOROVIRUS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
GENITAL FUNGAL INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
GUM INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	3 / 279 (1.08%)
occurrences (all)	1	4
GUT AT SACCHAROMYCES CEREVISIAE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
GUT AT STAPHYLOCOCCUS SP.		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HERPES INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
HERPES LABIALIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	1
HERPES SIMPLEX (MOUTH + VAGINAL)		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HERPES ZOSTER (MOUTH+VAGINAL)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
HIDRADENITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HSV INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ILEAL INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INFECTION TOE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INTESTINE INFECTION (CLOSTRIDIUM DIFFICILE)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
INVASIVE ASPERGILLOSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
JOINT INFECTION (MTP1 RIGHT)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

LARYNGITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
LINGUAL INFECTION (CANDIDIASIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
LINGUAL MYCOSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
LIP INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	8 / 277 (2.89%)	7 / 279 (2.51%)
occurrences (all)	9	7
LUNG INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	23 / 277 (8.30%)	22 / 279 (7.89%)
occurrences (all)	30	29
LYMPH GLAND INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
MAXILLARY CELLULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
MOUTH INFECTION (CANDIDA ALBICANS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
MOUTH INFECTION (HERPES SIMPLEX)		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
MRSA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
MUCORMYCOSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
MUCOSAL INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)
occurrences (all)	4	1
NAIL INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
NOSE INFECTION (POSSIBLY HERPES)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ORAL INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
ORAL INFECTION (APTHOUS STOMATITIS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
ORAL INFECTION (HSV)		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
ORAL THRUSH		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
OTITIS MEDIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
PARODONTITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PERIANAL WOUND		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
PERINEAL CELLULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PERITONSILLAR ABSCESS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PHARYNGITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	5 / 279 (1.79%)
occurrences (all)	4	5
PHLEBITIS INFECTIVE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1

PROBABLE VIRAL INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
PROSTATE INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
PTLD		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
QUERVAIN'S THYROIDITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
R FOLLICULITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
R HERPES STOMATITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
RECTUM INFECTION (CANDIDAS ALBICANS)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
RHINITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
RHINITIS INFECTIVE		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	4 / 277 (1.44%)	4 / 279 (1.43%)
occurrences (all)	4	4
RSV INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SALIVARY GLAND INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	3 / 279 (1.08%)
occurrences (all)	1	3
SEPSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	11 / 277 (3.97%)	18 / 279 (6.45%)
occurrences (all)	12	20
SEPTIC SHOCK		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	8 / 279 (2.87%)
occurrences (all)	4	9
SEPTIC SHOCK (ESCHERICHIA COLI)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SEPTIC SHOCK (PSEUDOMONAS AERUGINOSA)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SEPTIC SHOCK (PSEUDOMONAS AREUGINOSA)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SEPTICEMIA		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SINUSITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	10 / 277 (3.61%)	11 / 279 (3.94%)
occurrences (all)	11	11
SOFT PALATE INFECTION (HERPES)		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SKIN INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	9 / 277 (3.25%)	7 / 279 (2.51%)
occurrences (all)	9	16
STAPHYLOCOCCUS EPIDERMITIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
SOFT TISSUE INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	6	1
STAPHYLOCOCCUS HAEMOLYTICUS IN BLOOD		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
STREPTOCOCCUS PNEUMONIA SEPTICEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
SYSTEMIC CANDIDA		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
TENDINITIS QUADRICEPS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
TONSIL INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
TOOTH INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	6 / 279 (2.15%)
occurrences (all)	2	6
TOXOPLASMOSIS REACTIVATION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
UPPER RESPIRATORY INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	2 / 279 (0.72%)
occurrences (all)	4	2
UNSPECIFIED INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
URINARY TRACT INFECTION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	15 / 277 (5.42%)	9 / 279 (3.23%)
occurrences (all)	16	9
UROSEPSIS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1

<p>UTERINE INFECTION</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>VAGINAL INFECTION</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>WOUND INFECTION</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>VULVAL INFECTION</p> <p>alternative dictionary used: CTCAE 4.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>			
	0 / 277 (0.00%)	1 / 279 (0.36%)	
	0	1	
	3 / 277 (1.08%)	0 / 279 (0.00%)	
	4	0	
	0 / 277 (0.00%)	1 / 279 (0.36%)	
	0	1	
	0 / 277 (0.00%)	1 / 279 (0.36%)	
	0	1	
Metabolism and nutrition disorders			
ACIDOSIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)	
occurrences (all)	2	3	
ALKALOSIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	0 / 277 (0.00%)	2 / 279 (0.72%)	
occurrences (all)	0	2	
ANOREXIA			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	17 / 277 (6.14%)	26 / 279 (9.32%)	
occurrences (all)	22	33	
CARBON DIOXIDE NARCOSIS			
alternative dictionary used: CTCAE 4.0			
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)	
occurrences (all)	1	0	
C-REACTIVE PROTEIN INCREASED			
alternative dictionary used: CTCAE 4.0			

subjects affected / exposed	2 / 277 (0.72%)	3 / 279 (1.08%)
occurrences (all)	4	3
C-REACTIVE-PROTEIN INCREASED		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
CRP INCREASE		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	0 / 279 (0.00%)
occurrences (all)	3	0
CRP INCREASED		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	6 / 277 (2.17%)	7 / 279 (2.51%)
occurrences (all)	21	19
DENUTRITION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
DIABETES MELLITUS		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	2
DYSREGULATED GLYCEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	3
GLYCEMIC DISORDER		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HYPERGLYCEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	6 / 277 (2.17%)	5 / 279 (1.79%)
occurrences (all)	9	6

HYPERKALEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HYPERNATREMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	1
HYPERPHOSPHATAEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0
HYPOALBUMINEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	3
HYPOCALCEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	3 / 279 (1.08%)
occurrences (all)	1	3
HYPOGLYCEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	2	0
HYPOKALEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	5 / 279 (1.79%)
occurrences (all)	2	7
HYPOMAGNESEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	1 / 279 (0.36%)
occurrences (all)	1	1
HYPONATREMIA		
alternative dictionary used: CTCAE 4.0		

subjects affected / exposed	3 / 277 (1.08%)	1 / 279 (0.36%)
occurrences (all)	3	1
HYPOPHOSPHATEMIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	4 / 277 (1.44%)	2 / 279 (0.72%)
occurrences (all)	4	3
MALNUTRITION		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	1
POLYDYSPIA		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
PROSTATIC SPECIFIC ANTIGEN INCREASED		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	0 / 277 (0.00%)	1 / 279 (0.36%)
occurrences (all)	0	1
TUMOR LYSIS SYNDROME		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	2 / 277 (0.72%)	1 / 279 (0.36%)
occurrences (all)	2	1
ZINC AND COPPER DEFICIENCY		
alternative dictionary used: CTCAE 4.0		
subjects affected / exposed	1 / 277 (0.36%)	0 / 279 (0.00%)
occurrences (all)	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 July 2014	<p>The purpose of this amendment is to:</p> <ul style="list-style-type: none">- To add a central review of CT scans reported with abnormal findings. This will help the Data Review Committee for the patients review- To include a definition of fever- To reduce the amount of information collected about concomitant medication- To clarify the definition of an SAE in case patients who do not receive caspofungin- To enlarge the randomization period from 3 days to 4 days after start of chemo (to avoid issues when patients start close to the weekend)- To correct small inconsistencies <p>This amendment is a scientific amendment</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

At the interim analysis time, the survival rate at day 42 in the control arm was 94% and the new sample size should have been of 1280 patients. This was judged impossible both for logistical and financial reasons. Current analysis is underpowered.

Notes: