Clinical trial results:
10-day decitabine versus conventional chemotherapy (“3+7”) followed by allografting in AML patients 60+ years: a randomized phase III study of the EORTC Leukemia Group, CELG, GIMEMA and German MDS Study Group

Summary

EudraCT number	2014-001486-27
Trial protocol	BE DE PT LT SK BG NL IT FR
Global end of trial date	29 March 2024

Results information

Result version number	v1 (current)
This version publication date	18 August 2024
First version publication date	18 August 2024

Trial information

Trial identification

Sponsor protocol code	1301-LG

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02172872
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	European Organisaton for the Research and Treatment of Cancer (EORTC)
Sponsor organisation address	Av E. Mounier 83/11, Brussels, Belgium,
Public contact	Clinical Operations Department, European Organisaton for the Research and Treatment of Cancer (EORTC) , +32 27741072, regulatory@eortc.org
Scientific contact	Clinical Operations Department, European Organisaton for the Research and Treatment of Cancer (EORTC) , +32 27741072, 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	07 March 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the effect of 10-day decitabine at a dose of 20 mg/m2 versus conventional induction chemotherapy (“3+7”) on overall survival (OS) in older AML patients.

Protection of trial subjects:

This study was conducted in agreement with the Declaration of Helsinki and the laws and regulations of the participating countries. The protocol has been written and the study conducted according to the ICH Harmonized Tripartite Guideline on Good Clinical Practice. The protocol has been approved by the competent ethics committee(s) as required by the applicable national legislation.

Background therapy: -

Evidence for comparator:

The combination of cytarabine and an anthracycline has been the standard of care for patients with AML for the last 4 decades. However, the application of this regimen in the elderly population does not yield similar results to those reported for younger patients.

In the HOVON43 study, patients 60 years of age or older were randomly assigned to receive cytarabine at a dose of 200 mg/m2 by continuous infusion for 7 days plus daunorubicin for 3 days, either at the conventional dose of 45 mg/m2 or at an escalated dose of 90 mg/m2. The OS was similar between the two groups and the median OS of all included patients was estimated to be about 11 months.

In the EORTC-GIMEMA AML-17 study conducted in older AML patients, the median OS was 10 months in the standard arm (MICE followed by 2 x mini-ICE) .

Actual start date of recruitment	31 October 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 140
Country: Number of subjects enrolled	Portugal: 5
Country: Number of subjects enrolled	Belgium: 33
Country: Number of subjects enrolled	Bulgaria: 2
Country: Number of subjects enrolled	France: 62
Country: Number of subjects enrolled	Germany: 161
Country: Number of subjects enrolled	Italy: 154
Country: Number of subjects enrolled	Lithuania: 27
Country: Number of subjects enrolled	Croatia: 22

Worldwide total number of subjects	606
EEA total number of subjects	606

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)	151
From 65 to 84 years	455
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Between 2014 and 2019, 606 patients were enrolled.

Pre-assignment

Screening details:

In total, 633 patients were screened for eligibility.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Decitabine

Arm description:

Decitabine according to the 10-day schedule

Arm type	Experimental
Investigational medicinal product name	Decitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

20 mg/m2 via a one hour infusion on ten consecutive days in each cycle of 28 days. During cycles 2 and 3, reduced to 5 days in case of a remission (<5% blasts in the bone marrow). From cycle 4 onwards, reduced to 5 days, as long as there is no evidence of progression.

Arm title	"3+7"

Arm description:

Standard chemotherapy

Arm type	Active comparator
Investigational medicinal product name	Daunorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

60 mg/m2 on days 1, 2, 3 during cycle 1 and 45 mg/m2 on days 1, 2, 3 during cycle 2.

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

200 mg/m2 continuous infusion (24 hours) during days 1-7 of cycles 1 and 2.

Number of subjects in period 1	Decitabine	"3+7"
Started	303	303
Completed	303	303

Period 2	
Period 2 title	Protocol treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Decitabine

Arm description:

Decitabine according to the 10-day schedule

Arm type	Experimental
Investigational medicinal product name	Decitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

20 mg/m2 via a one hour infusion on ten consecutive days in each cycle of 28 days. During cycles 2 and 3, reduced to 5 days in case of a remission (<5% blasts in the bone marrow). From cycle 4 onwards, reduced to 5 days, as long as there is no evidence of progression.

Arm title	"3+7"

Arm description:

Standard chemotherapy

Arm type	Active comparator
Investigational medicinal product name	Daunorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

60 mg/m2 on days 1, 2, 3 during cycle 1 and 45 mg/m2 on days 1, 2, 3 during cycle 2.

Investigational medicinal product name	Cytarabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

200 mg/m2 continuous infusion (24 hours) during days 1-7 of cycles 1 and 2.

Number of subjects in period 2[1]	Decitabine	"3+7"
Started	302	298
Completed	123	143
Not completed	179	155
Toxicity	14	44
Other	4	8
Death not due to AML or toxicity	6	4
Treatment failure/relapse	129	61
Treatment failure and toxicity	4	5
Other malignancy	3	-
Patient's decision	11	14
Start of new treatment	8	19

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: 1 patient in the decitabine arm and 5 patients in the 3+7 arm did not start the protocol treatment.

Baseline characteristics

Reporting groups	
Reporting group title	Randomization

Reporting group description: -

Reporting group values	Randomization	Total	
Number of subjects	606	606	
Age categorical Units: Subjects			
60-64	151	151	
65-69	251	251	
70 or older	204	204	
Age continuous Units: years			
median	68		
inter-quartile range (Q1-Q3)	60 to 81	-	
Gender categorical Units: Subjects			
Female	258	258	
Male	345	345	
Unknown	3	3	
ELN 2017 Units: Subjects			
Favorable	115	115	
Intermediate	257	257	
Adverse	178	178	
Missing	56	56	

End points

End points reporting groups

Reporting group title	Decitabine
Reporting group description: Decitabine according to the 10-day schedule	
Reporting group title	"3+7"
Reporting group description: Standard chemotherapy	
Reporting group title	Decitabine
Reporting group description: Decitabine according to the 10-day schedule	
Reporting group title	"3+7"
Reporting group description: Standard chemotherapy	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description: All randomized patients	
Subject analysis set title	Patients who achieved CR/CRi
Subject analysis set type	Sub-group analysis
Subject analysis set description: This set included patients who achieved CR/CRi during the protocol treatment and was used to describe outcomes from reaching CR/CRi.	
Subject analysis set title	Patients who were allografted
Subject analysis set type	Sub-group analysis
Subject analysis set description: This set included patients who underwent allo-HSCT and was used to describe outcomes after allo-HSCT.	

Primary: Overall survival

End point title	Overall survival
End point description: Time from randomization to death.	
End point type	Primary
End point timeframe: From randomization	

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	303	303		
Units: % at 4 years				
number (confidence interval 95%)	26.0 (20.8 to 31.5)	29.7 (24.3 to 35.3)		

Statistical analyses

Statistical analysis title	Primary OS analysis
Comparison groups	Decitabine v "3+7"
Number of subjects included in analysis	606
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.26

Secondary: Progression-free survival	
End point title	Progression-free survival
End point description: Time from randomization to progression or death, whichever comes first.	
End point type	Secondary
End point timeframe: From randomization	

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	303	303		
Units: % at 4 years				
number (confidence interval 95%)	22.5 (17.6 to 27.7)	23.9 (18.7 to 29.5)		

Statistical analyses

Statistical analysis title	Primary PFS analysis
Comparison groups	Decitabine v "3+7"
Number of subjects included in analysis	606
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Hazard ratio (HR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.32

Secondary: Overall CR/CRi	
End point title	Overall CR/CRi
End point description:	
Documented CR/CRi during protocol or post-protocol treatments prior to allografting.	
End point type	Secondary
End point timeframe:	
Protocol or post-protocol treatments prior to allografting	

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	303	303		
Units: Yes or no based on ELN 2017 cirteria				
CR/CRi	183	203		
No CR/CRi	120	100		

Statistical analyses

Statistical analysis title	Primary overall CR/CRi rate analysis
Statistical analysis description:	
Values of the odds ratio lower than 1 indicate a higher probability of CR/CRi in the 3+7 arm.	
Comparison groups	Decitabine v "3+7"
Number of subjects included in analysis	606
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.05

Secondary: CR/CRi	
End point title	CR/CRi
End point description:	
Documented CR/CRi during protocol treatment prior to allografting.	
End point type	Secondary
End point timeframe:	
During protocol treatment prior to allografting	

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	303	303		
Units: Yes versus no based on ELN 2017 criteria				
CR/CRi	145	186		
No CR/CRi	158	117		

Statistical analyses

Statistical analysis title	Primary CR/CRi rate analysis
Statistical analysis description:	
Values of the odds ratio smaller than 1 indicate a higher probability of reaching CR/CRi in the 3+7 arm.	
Comparison groups	Decitabine v "3+7"
Number of subjects included in analysis	606
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	0.8

Secondary: Response

End point title	Response
End point description:	
Documented response during protocol treatment prior to allografting.	
End point type	Secondary
End point timeframe:	
During protocol treatment prior to allografting	

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	303	303		
Units: Yes or no based on ELN 2017				
PR, MLFS, or CR/CRi	173	204		
No PR, MLFS, or CR/CRi	130	99		

Statistical analyses

Statistical analysis title	Primary response analysis
Statistical analysis description:	
Values of the odds ratio smaller than 1 indicate a higher probability of response in the 3+7 arm.	
Comparison groups	Decitabine v "3+7"
Number of subjects included in analysis	606
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	0.9

Secondary: Allografting

End point title	Allografting
End point description:	
Undergoing allo-HSCT following decitabine or 3+7.	
End point type	Secondary
End point timeframe:	
Protocol treatment	

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	303	303		
Units: Yes versus no				
Allografting as a part of the protocol treatment	122	118		
No allografting as a part of the protocol	181	185		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of hospitalization

End point title	Duration of hospitalization

End point description:

The number of days of hospitalization during the first 3 cycles of the treatment. This information was collected only in a subgroup of patients.

End point type	Secondary

End point timeframe:

Cycles 1, 2, and 3

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	84		
Units: Days				
arithmetic mean (inter-quartile range (Q1-Q3))	40 (21 to 60)	52 (33 to 63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Disease-free survival from CR/CRi

End point title	Disease-free survival from CR/CRi

End point description:

Time between CR/CRi and relapse or death, whichever occurred first. This endpoint was analyzed among patients who achieved CR/CRi during the protocol treatment and prior to allografting.

End point type	Secondary

End point timeframe:

From CR/CRi

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	186		
Units: % at 4 years				
number (confidence interval 95%)	27.6 (19.7 to 36.1)	31.8 (24.5 to 39.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to relapse from CR/CRi

End point title	Time to relapse from CR/CRi

End point description:

Time to relapse from CR/CRi. Death without a relapse was treated as a competing event in the analysis. This endpoint was analyzed among patients who achieved CR/CRi during the protocol treatment and prior to allografting.

End point type	Secondary

End point timeframe:

From CR/CRi

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	186		
Units: % with a relapse at 4 years				
number (confidence interval 95%)	52.2 (42.8 to 60.7)	42.5 (34.7 to 50.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to death without relapse from CR/CRi

End point title	Time to death without relapse from CR/CRi

End point description:

Time to death without relapse from CR/CRi. Relapse was treated as a competing event in the analysis. This endpoint was analyzed among patients who achieved CR/CRi during the protocol treatment and prior to allografting.

End point type	Secondary

End point timeframe:

From CR/CRi

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	186		
Units: % who died without relapse at 4 years				
number (confidence interval 95%)	20.2 (13.8 to 27.6)	25.6 (19.3 to 32.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: PFS from allo-HSCT

End point title	PFS from allo-HSCT

End point description:

Time to progression or death from allo-HSCT, whichever occurred first. This endpoint was analyzed among patients who received allo-HSCT as a part of the protocol treatment.

End point type	Secondary

End point timeframe:

From allo-HSCT

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	118		
Units: % at 4 years				
number (confidence interval 95%)	45.2 (35.1 to 54.7)	44.2 (34.3 to 53.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to progression from allo-HSCT

End point title	Time to progression from allo-HSCT

End point description:

This endpoint was analyzed among patients who received allo-HSCT as a part of the protocol treatment. Death without progression was treated as a competing event in the analysis.

End point type	Secondary

End point timeframe:

From allo-HSCT

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	118		
Units: % with a progression at 4 years				
number (confidence interval 95%)	23.8 (16.4 to 31.9)	22.4 (14.8 to 31.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to death without progression from allo-HSCT

End point title	Time to death without progression from allo-HSCT

End point description:

This endpoint was analyzed among patients who received allo-HSCT as a part of the protocol treatment. Progression was treated as a competing event in the analysis.

End point type	Secondary

End point timeframe:

From allo-HSCT

End point values	Decitabine	"3+7"		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	118		
Units: % who died without progression				
number (confidence interval 95%)	31.1 (22.1 to 40.4)	33.4 (24.5 to 42.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Information about all adverse events was collected between randomization and 30 days after last dose of the protocol drug treatment (decitabine or 3+7) or first day of hospitalization for transplantation, whichever occurred first.

Adverse event reporting additional description:

Information about SAEs related to the transplantation procedure concerning graft failure, SOS, grade 3-4 infections, and toxic deaths was reported until the end of the study. Information about SAEs related to the protocol drug treatment decitabine or 3+7 was reported until the end of the study as well.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19

Reporting groups

Reporting group title	"3+7"
Reporting group description: -	
Reporting group title	Decitabine

Reporting group description: -

Serious adverse events	"3+7"	Decitabine	
Total subjects affected by serious adverse events			
subjects affected / exposed	125 / 298 (41.95%)	160 / 302 (52.98%)	
number of deaths (all causes)	221	230	
number of deaths resulting from adverse events	51	41	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ACUTE MYELOID LEUKAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
INVASIVE BREAST CARCINOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MIXED ADENONEUROENDOCRINE CARCINOMA			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
RENAL CANCER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CELL CARCINOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
UTERINE CANCER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Vascular disorders			
VENOOCCLUSIVE DISEASE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
VASCULITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOPHLEBITIS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBCLAVIAN VEIN THROMBOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PHLEBITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ISCHAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORTHOSTATIC HYPOTENSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EMBOLISM			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEEP VEIN THROMBOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Surgical and medical procedures			
EUTHANASIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
General disorders and administration site conditions			
CHEST PAIN			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASTHENIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYST			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED THROMBOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERAL PHYSICAL HEALTH DETERIORATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	1 / 2	2 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
MUCOSAL INFLAMMATION			

alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	17 / 298 (5.70%)	10 / 302 (3.31%)	
occurrences causally related to treatment / all	15 / 17	7 / 10	
deaths causally related to treatment / all	15 / 17	7 / 10	
PYREXIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUDDEN DEATH			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
DEATH			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
Immune system disorders			
GRAFT VERSUS HOST DISEASE IN LIVER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE GRAFT VERSUS HOST DISEASE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	1 / 1	2 / 2	
ACUTE GRAFT VERSUS HOST DISEASE IN INTESTINE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
ACUTE GRAFT VERSUS HOST DISEASE IN LIVER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
ANAPHYLACTIC REACTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC GRAFT VERSUS HOST DISEASE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
GRAFT VERSUS HOST DISEASE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	7 / 302 (2.32%)	
occurrences causally related to treatment / all	1 / 1	6 / 7	
deaths causally related to treatment / all	0 / 0	6 / 7	
GRAFT VERSUS HOST DISEASE IN GASTROINTESTINAL TRACT			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	2 / 298 (0.67%)	4 / 302 (1.32%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	1 / 1	4 / 4	
GRAFT VERSUS HOST DISEASE IN LUNG			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GRAFT VERSUS HOST DISEASE IN SKIN			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
INTERSTITIAL LUNG DISEASE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
IDIOPATHIC PNEUMONIA SYNDROME			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE RESPIRATORY FAILURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	1 / 1	1 / 2	
ACUTE RESPIRATORY DISTRESS SYNDROME			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	1 / 2	0 / 0	
ACUTE PULMONARY OEDEMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	1 / 3	0 / 0	
ORGANISING PNEUMONIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	1 / 3	2 / 3	
deaths causally related to treatment / all	1 / 1	0 / 0	
PULMONARY ALVEOLAR HAEMORRHAGE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY OEDEMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
PULMONARY VASCULITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY VENO-OCCLUSIVE DISEASE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
RESPIRATORY DISTRESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY FAILURE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	6 / 298 (2.01%)	7 / 302 (2.32%)	
occurrences causally related to treatment / all	2 / 6	1 / 7	
deaths causally related to treatment / all	2 / 4	1 / 5	
PLEURAL EFFUSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
DELIRIUM			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DELUSIONAL DISORDER, UNSPECIFIED TYPE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
TRANSAMINASES INCREASED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPHIL COUNT DECREASED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD CREATININE INCREASED			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
SPINAL COMPRESSION FRACTURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPLENIC RUPTURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMUR FRACTURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FALL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EXTRADURAL HAEMATOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
INJURY			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSPLANT FAILURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	1 / 1	2 / 3	
deaths causally related to treatment / all	1 / 1	0 / 0	
Congenital, familial and genetic disorders			
HEART DISEASE CONGENITAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
SINUS BRADYCARDIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARRHYTHMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FIBRILLATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL TACHYCARDIA			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ARREST			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	4 / 302 (1.32%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 3	
CARDIAC FAILURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	6 / 302 (1.99%)	
occurrences causally related to treatment / all	3 / 3	0 / 6	
deaths causally related to treatment / all	1 / 1	0 / 1	
CARDIAC FAILURE CONGESTIVE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
DILATED CARDIOMYOPATHY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL INFARCTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL ISCHAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

PERICARDITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RIGHT VENTRICULAR DYSFUNCTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STRESS CARDIOMYOPATHY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOXIC CARDIOMYOPATHY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR FIBRILLATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TACHYCARDIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
DIZZINESS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 2	
CEREBROVASCULAR ACCIDENT			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 1	1 / 2	
TOXIC ENCEPHALOPATHY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNCOPE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBARACHNOID HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OPTIC NEURITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

MEMORY IMPAIRMENT			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ISCHAEMIC STROKE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
HEPATIC ENCEPHALOPATHY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGE INTRACRANIAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Blood and lymphatic system disorders			
ANAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	2 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BONE MARROW FAILURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
FEBRILE NEUTROPENIA			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	2 / 298 (0.67%)	26 / 302 (8.61%)	
occurrences causally related to treatment / all	3 / 3	24 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
LEUKOCYTOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
LEUKOSTASIS SYNDROME			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	5 / 302 (1.66%)	
occurrences causally related to treatment / all	1 / 1	4 / 5	
deaths causally related to treatment / all	1 / 1	0 / 0	
PANCYTOPENIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
SPLENIC HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

FEBRILE BONE MARROW APLASIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	5 / 302 (1.66%)	
occurrences causally related to treatment / all	1 / 1	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ANORECTAL DISORDER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
CONSTIPATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIARRHOEA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOLITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
GASTROINTESTINAL HAEMORRHAGE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
GASTROINTESTINAL INFLAMMATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINAL OBSTRUCTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINE PERFORATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIC COLITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
PANCREATITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

PEPTIC ULCER HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLECYSTITIS ACUTE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLESTASIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRUG-INDUCED LIVER INJURY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
HEPATIC FAILURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	2 / 2	0 / 0	
PORTAL HYPERTENSION			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
ACUTE FEBRILE NEUTROPHILIC DERMATOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
RENAL FAILURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
CYSTITIS HAEMORRHAGIC			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC KIDNEY DISEASE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE KIDNEY INJURY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
Musculoskeletal and connective tissue disorders			
BACK PAIN			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYALGIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
CYTOMEGALOVIRUS COLITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
ANAL ABSCESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANAL INFECTION			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRITIS BACTERIAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASPERGILLUS INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERIAL INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERIAL SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
BRONCHITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

BRONCHOPULMONARY ASPERGILLOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CANDIDA INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAT SCRATCH DISEASE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE COLITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORYNEBACTERIUM SEPSIS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYSTITIS VIRAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYTOMEGALOVIRUS INFECTION REACTIVATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
DEVICE RELATED INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
ECTHYMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENCEPHALITIS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 2	
ENCEPHALITIS VIRAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
ENTEROBACTER SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOCCAL BACTERAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
ENTEROCOCCAL SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
EPSTEIN-BARR VIRUS INFECTION REACTIVATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA BACTERAEMIA			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
FUNGAL INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS CLOSTRIDIAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GROIN INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC INFECTION FUNGAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
HEPATOSPLENIC CANDIDIASIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

HERPES VIRUS INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFLUENZA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
KLEBSIELLA BACTERAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER RESPIRATORY TRACT INFECTION FUNGAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SINUSITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SERRATIA INFECTION			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPTIC SHOCK			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	20 / 298 (6.71%)	9 / 302 (2.98%)	
occurrences causally related to treatment / all	15 / 21	6 / 9	
deaths causally related to treatment / all	8 / 10	4 / 6	
SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	27 / 298 (9.06%)	20 / 302 (6.62%)	
occurrences causally related to treatment / all	29 / 31	13 / 20	
deaths causally related to treatment / all	15 / 17	6 / 11	
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
PULMONARY MUCORMYCOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
PSEUDOMONAS INFECTION			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
PSEUDOMONAL SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
PNEUMONIA FUNGAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	2 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
PNEUMONIA ESCHERICHIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
PNEUMONIA BACTERIAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
PNEUMONIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	25 / 298 (8.39%)	27 / 302 (8.94%)	
occurrences causally related to treatment / all	19 / 26	22 / 30	
deaths causally related to treatment / all	10 / 11	3 / 8	
PNEUMOCYSTIS JIROVECII PNEUMONIA			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOCYSTIS JIROVECII INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
PERITONITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIC SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIC INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCLE ABSCESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG ABSCESS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL UPPER RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UROSEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION BACTERIAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOOTH INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOOTH ABSCESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TESTICULAR ABSCESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYSTEMIC MYCOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 298 (1.01%)	2 / 302 (0.66%)	
occurrences causally related to treatment / all	1 / 3	1 / 2	
deaths causally related to treatment / all	1 / 2	1 / 2	
STREPTOCOCCAL SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STREPTOCOCCAL INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

STOMATOCOCCAL INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
STAPHYLOCOCCAL INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
HYPOKALAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	4 / 302 (1.32%)	
occurrences causally related to treatment / all	1 / 1	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERNATRAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
DEHYDRATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DECREASED APPETITE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LACTIC ACIDOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
HYPERVOLAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	"3+7"	Decitabine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	284 / 298 (95.30%)	285 / 302 (94.37%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ENDOCRINE DISORDERS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
EPIDURAL CYST LESION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
NEOPLASMS MALIGNANT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			

ANEURYSMA ASCENDENS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
CALCIFIC PLAQUE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
CAPILLARY LEAK SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
FLUSHING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
HEMATOMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 298 (2.35%)	12 / 302 (3.97%)	
occurrences (all)	7	14	
HOT FLASHES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	3 / 302 (0.99%)	
occurrences (all)	3	3	
HYPERTENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	15 / 298 (5.03%)	19 / 302 (6.29%)	
occurrences (all)	17	19	
HYPOTENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	6 / 298 (2.01%)	6 / 302 (1.99%)	
occurrences (all)	8	6	
LYMPHEDEMA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	4 / 298 (1.34%)	1 / 302 (0.33%)	
occurrences (all)	5	1	
PERIPHERAL ISCHEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PHLEBITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	7 / 302 (2.32%)	
occurrences (all)	3	7	
PSEUDOANEURYSM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
SUPERFICIAL THROMBOPHLEBITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	2 / 302 (0.66%)	
occurrences (all)	5	2	
THROMBOEMBOLIC EVENT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	15 / 298 (5.03%)	10 / 302 (3.31%)	
occurrences (all)	17	11	
VASCULITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	1 / 302 (0.33%)	
occurrences (all)	4	1	
VARICOSE VEIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
FEVER			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	80 / 298 (26.85%)	58 / 302 (19.21%)	
occurrences (all)	127	79	
BLEEDING ON CENTRAL VENOUS CATHETER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
CHILLS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	2 / 302 (0.66%)	
occurrences (all)	5	2	
DECREASED INDEPENDENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
DECREASED MOBILITY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
EDEMA FACE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences (all)	3	0	
EDEMA LIMBS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	51 / 298 (17.11%)	31 / 302 (10.26%)	
occurrences (all)	64	39	
FACIAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
FATIGUE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	29 / 298 (9.73%)	41 / 302 (13.58%)	
occurrences (all)	41	56	

FLU LIKE SYMPTOMS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences (all)	1	3	
GENERAL DETERIORATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	1 / 302 (0.33%)	
occurrences (all)	7	1	
GENERAL EDEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
INFUSION RELATED REACTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	6 / 298 (2.01%)	2 / 302 (0.66%)	
occurrences (all)	8	2	
INFUSION SITE EXTRAVASATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
INJECTION SITE REACTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	5 / 302 (1.66%)	
occurrences (all)	3	6	
IRRITABILITY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
LOCALIZED EDEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	6 / 298 (2.01%)	6 / 302 (1.99%)	
occurrences (all)	7	8	
MALAISE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	4 / 298 (1.34%)	9 / 302 (2.98%)	
occurrences (all)	4	13	
NON-CARDIAC CHEST PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 298 (3.02%)	6 / 302 (1.99%)	
occurrences (all)	9	6	
PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	4 / 302 (1.32%)	
occurrences (all)	4	4	
PAIN (AFTER SURGERY)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PROGRESSIVE DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	2	
ULCER IN PICC SITE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
GAIT DISTURBANCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
Immune system disorders			
GRAFT VERSUS HOST DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	3 / 302 (0.99%)	
occurrences (all)	6	4	
ALLERGIC REACTION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	16 / 298 (5.37%)	12 / 302 (3.97%)	
occurrences (all)	21	12	
ALLO PLATELET IMMUNIZATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
ANAPHYLAXIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
CYTOKINE RELEASE SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
IMMUNE RECONSTITUTION INFLAMMATORY SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
INFLAMMATORY SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
IMMUNE SYSTEM DISORDER (ERYTHEMA NODOSUM)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
LESION OEDEMATOUS OF PUBIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
GYNECOMASTIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
GENITAL EDEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
FEMALE GENITAL TRACT FISTULA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
MENORRHAGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PELVIC PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PROSTATIC HYPERPLASIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
VAGINAL INFLAMMATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
TESTICULAR DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PROSTATIC PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	

PROSTATIC OBSTRUCTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PROSTATIC HYPERTROPHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
PLEURAL EFFUSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	13 / 298 (4.36%)	16 / 302 (5.30%)	
occurrences (all)	13	18	
PHARYNGOLARYNGEAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PHARYNGEAL MUCOSITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
NASAL CONGESTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	2 / 302 (0.66%)	
occurrences (all)	2	2	
LARYNGEAL MUCOSITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
LARYNGEAL INFLAMMATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
HYPOXIA			
alternative dictionary used: CTCAE			

4			
subjects affected / exposed	7 / 298 (2.35%)	4 / 302 (1.32%)	
occurrences (all)	7	4	
HOARSENESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
HICCUPS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences (all)	3	0	
HEMOPTYSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
GRANULOMA OF THE LUNG			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
EPISTAXIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	26 / 298 (8.72%)	28 / 302 (9.27%)	
occurrences (all)	34	45	
DYSPNEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	23 / 298 (7.72%)	37 / 302 (12.25%)	
occurrences (all)	25	44	
CREPITATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
COUGH			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	8 / 298 (2.68%)	21 / 302 (6.95%)		
occurrences (all)	8	25		
COPD EXACERBATION				
alternative dictionary used: CTCAE 4				
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)		
occurrences (all)	1	0		
ASPIRATION				
alternative dictionary used: CTCAE 4				
subjects affected / exposed	4 / 298 (1.34%)	1 / 302 (0.33%)		
occurrences (all)	4	1		
ALLERGIC RHINITIS				
alternative dictionary used: CTCAE 4				
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)		
occurrences (all)	0	1		
ADULT RESPIRATORY DISTRESS SYNDROME				
alternative dictionary used: CTCAE 4				
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)		
occurrences (all)	1	2		
SORE THROAT				
alternative dictionary used: CTCAE 4				
subjects affected / exposed	2 / 298 (0.67%)	4 / 302 (1.32%)		
occurrences (all)	2	4		
PULMONARY MICRONODULES				
alternative dictionary used: CTCAE 4				
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)		
occurrences (all)	0	1		
PULMONARY INTERSTITIAL SYNDROM				
alternative dictionary used: CTCAE 4				
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)		
occurrences (all)	0	1		
PULMONARY EDEMA				
alternative dictionary used: CTCAE 4				

subjects affected / exposed	7 / 298 (2.35%)	10 / 302 (3.31%)	
occurrences (all)	7	10	
PRODUCTIVE COUGH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
PNEUMOTHORAX			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
PNEUMONITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 298 (2.35%)	6 / 302 (1.99%)	
occurrences (all)	8	6	
PLEURITIC PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
Psychiatric disorders			
PSYCHIATRIC DISORDERS NOS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
MANIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
INSOMNIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 298 (2.35%)	8 / 302 (2.65%)	
occurrences (all)	8	9	
HALLUCINATIONS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	4 / 298 (1.34%)	2 / 302 (0.66%)	
occurrences (all)	4	2	
DEPRESSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	3 / 302 (0.99%)	
occurrences (all)	3	4	
DELIRIUM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	5 / 302 (1.66%)	
occurrences (all)	4	6	
CONFUSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	5 / 302 (1.66%)	
occurrences (all)	7	6	
ANXIETY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 298 (2.35%)	3 / 302 (0.99%)	
occurrences (all)	7	3	
AGITATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences (all)	1	2	
Investigations			
URINE OUTPUT DECREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PLATELET COUNT INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PLATELET COUNT DECREASED			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	92 / 298 (30.87%)	75 / 302 (24.83%)	
occurrences (all)	326	202	
NEUTROPHIL COUNT DECREASED alternative dictionary used: CTCAE 4			
subjects affected / exposed	39 / 298 (13.09%)	57 / 302 (18.87%)	
occurrences (all)	93	143	
LYMPHOCYTE COUNT DECREASED alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences (all)	4	0	
HYPERFERRITINEMIA alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
GGT INCREASED alternative dictionary used: CTCAE 4			
subjects affected / exposed	23 / 298 (7.72%)	23 / 302 (7.62%)	
occurrences (all)	39	40	
FIBRINOGEN DECREASED alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
ELECTROCARDIOGRAM QT CORRECTED INTERVAL PROLONGED alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
EJECTION FRACTION DECREASED alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
D DIMERE INCREASED alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	

CRP INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	19 / 298 (6.38%)	16 / 302 (5.30%)	
occurrences (all)	23	23	
CREATININE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	10 / 298 (3.36%)	6 / 302 (1.99%)	
occurrences (all)	15	11	
CARDIAC TROPONIN T INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
BLOOD BILIRUBIN INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	8 / 298 (2.68%)	8 / 302 (2.65%)	
occurrences (all)	11	15	
ASPARTATE AMINOTRANSFERASE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	12 / 298 (4.03%)	16 / 302 (5.30%)	
occurrences (all)	14	21	
ANTITHROMBIN DECREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
ALKALINE PHOSPHATASE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	13 / 298 (4.36%)	8 / 302 (2.65%)	
occurrences (all)	22	11	
ALANINE AMINOTRANSFERASE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	13 / 298 (4.36%)	20 / 302 (6.62%)	
occurrences (all)	19	31	
ACTIVATED PARTIAL THROMBOPLASTIN TIME			

PROLONGED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
WHITE BLOOD CELL DECREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 298 (3.02%)	8 / 302 (2.65%)	
occurrences (all)	17	16	
WEIGHT LOSS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	99 / 298 (33.22%)	97 / 302 (32.12%)	
occurrences (all)	125	121	
WEIGHT GAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	17 / 298 (5.70%)	13 / 302 (4.30%)	
occurrences (all)	23	13	
Injury, poisoning and procedural complications			
BRAIN TRAUMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
BRUISING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences (all)	0	4	
FALL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 298 (3.02%)	5 / 302 (1.66%)	
occurrences (all)	11	5	
FRACTURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
INJURY RIGHT HAND			
alternative dictionary used: CTCAE			

4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
INTRAOPERATIVE RESPIRATORY INJURY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
POSTOPERATIVE HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
SEROMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
SPINAL FRACTURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
WRIST FRACTURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
TACROLIMUS OVERDOSE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
TRACHEAL OBSTRUCTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
VASCULAR ACCESS COMPLICATION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	3 / 298 (1.01%)	2 / 302 (0.66%)	
occurrences (all)	3	2	
Cardiac disorders			
PALPITATIONS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
ACUTE CORONARY SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
ATRIAL FIBRILLATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	21 / 298 (7.05%)	15 / 302 (4.97%)	
occurrences (all)	25	15	
ATRIAL FLUTTER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences (all)	1	2	
CHEST PAIN - CARDIAC			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
DILATATIVE CARDIOMYOPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
ECG ALTERATION/ NEGATIVE P WAVES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
EXTRASYSTOLES			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
HEART FAILURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	6 / 302 (1.99%)	
occurrences (all)	4	8	
LEFT VENTRICULAR SYSTOLIC DYSFUNCTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
MITRAL VALVE DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
MYOCARDIAL INFARCTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
PAROXYSMAL ATRIAL TACHYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
RESTRICTIVE CARDIOMYOPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
RIGHT VENTRICULAR DYSFUNCTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
SINUS BRADYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	2	0	

SINUS TACHYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	4 / 302 (1.32%)	
occurrences (all)	4	4	
SUPRAVENTRICULAR TACHYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
TACHYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
TRICUSPID VALVE DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
VENTRICULAR TACHYCARDIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
PERICARDIAL EFFUSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	5 / 302 (1.66%)	
occurrences (all)	2	5	
Nervous system disorders			
CENTRAL NERVOUS SYSTEM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
COGNITIVE DISTURBANCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
DEPRESSED LEVEL OF CONSCIOUSNESS			
alternative dictionary used: CTCAE			

4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
VASOVAGAL REACTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
DIZZINESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	14 / 302 (4.64%)	
occurrences (all)	2	15	
TRANSIENT ISCHEMIC ATTACKS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
SYNCOPE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 298 (3.02%)	6 / 302 (1.99%)	
occurrences (all)	9	6	
STROKE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
SOMNOLENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
SINUS PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
SEIZURE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
PRESYNCOPE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PERIPHERAL SENSORY NEUROPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	2 / 302 (0.66%)	
occurrences (all)	5	2	
PERIPHERAL MOTOR NEUROPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
PARESTHESIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	3 / 302 (0.99%)	
occurrences (all)	2	3	
OLFACTORY NERVE DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
NEURALGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
MEMORY IMPAIRMENT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
LETHARGY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	

INTRACRANIAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	2 / 302 (0.66%)	
occurrences (all)	3	2	
HYPERSOMNIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
HEADACHE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	37 / 298 (12.42%)	28 / 302 (9.27%)	
occurrences (all)	47	31	
EXTRAPYRAMIDAL DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
ENCEPHALOPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
EDEMA CEREBRAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
DYSGEUSIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	3 / 302 (0.99%)	
occurrences (all)	5	3	
DYSARTHRIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
TREMOR			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
ANEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	77 / 298 (25.84%)	76 / 302 (25.17%)	
occurrences (all)	327	303	
DISSEMINATED INTRAVASCULAR COAGULATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
FEBRILE NEUTROPENIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	170 / 298 (57.05%)	87 / 302 (28.81%)	
occurrences (all)	282	130	
LEUKOCYTOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
LYMPH NODE PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PANCYTOPENIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
PETECHIAE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
SPLEEN DISORDER			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
THROMBOTIC MICROANGIOPATHY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
THROMBOTIC THROMBOCYTOPENIC PURPURA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	5 / 302 (1.66%)	
occurrences (all)	1	5	
BONE MARROW HYPOCELLULAR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
EAR DISORDER PRESSURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
EAR PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	2 / 302 (0.66%)	
occurrences (all)	3	3	
EXTERNAL EAR INFLAMMATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
HEARING IMPAIRED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
MIDDLE EAR INFLAMMATION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
TINNITUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences (all)	0	3	
VERTIGO			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	3 / 302 (0.99%)	
occurrences (all)	5	3	
Eye disorders			
DRY EYE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	5 / 302 (1.66%)	
occurrences (all)	2	5	
BLEEDING LEFT EYE AND EXOPHTHALMOS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
BLURRED VISION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	4 / 302 (1.32%)	
occurrences (all)	4	4	
COLOUR VISION DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
CONJUNCTIVITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 298 (2.35%)	2 / 302 (0.66%)	
occurrences (all)	7	3	
CORNEAL ULCER			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
DIPLOPIA OR DOUBLE PICTURES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
EYE DISORDERS; CHALAZION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
EYE PRESSURE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
EYELID FUNCTION DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
FLASHING LIGHTS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
GLAUCOMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
RETINAL VASCULAR DISORDER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	2 / 302 (0.66%)	
occurrences (all)	2	2	
UVEITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	

VITREOUS HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
EYE PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
Gastrointestinal disorders			
DRY MOUTH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL DISTENSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	23 / 298 (7.72%)	14 / 302 (4.64%)	
occurrences (all)	26	16	
ANAL FISTULA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	3 / 302 (0.99%)	
occurrences (all)	1	3	
ANAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	3 / 302 (0.99%)	
occurrences (all)	2	3	
ANAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	4 / 302 (1.32%)	
occurrences (all)	0	6	
ANAL ULCER			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 298 (0.00%)	4 / 302 (1.32%)	
occurrences (all)	0	4	
ASCITES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
BLOATING			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
CHEILITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
COLITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 298 (3.02%)	2 / 302 (0.66%)	
occurrences (all)	9	3	
COLONIC STENOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
CONSTIPATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	51 / 298 (17.11%)	46 / 302 (15.23%)	
occurrences (all)	57	54	
DIARRHEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	168 / 298 (56.38%)	64 / 302 (21.19%)	
occurrences (all)	238	90	
DISCOLORATION OF THE TONGUE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	

DIVERTICULA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
DUODENAL ULCER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
ORAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	3 / 302 (0.99%)	
occurrences (all)	3	5	
DYSPHAGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
ENTEROCOLITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	10 / 298 (3.36%)	0 / 302 (0.00%)	
occurrences (all)	10	0	
ESOPHAGEAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
ESOPHAGEAL ULCER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
ESOPHAGITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
FLATULENCE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
GASTRIC HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	0 / 302 (0.00%)	
occurrences (all)	3	0	
GASTRIC MUCOSITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
GASTRIC ULCER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
GASTRITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
GASTROESOPHAGEAL REFLUX DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 298 (2.35%)	3 / 302 (0.99%)	
occurrences (all)	8	4	
GASTROINTESTINAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	5 / 302 (1.66%)	
occurrences (all)	2	5	
GINGIVAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences (all)	1	2	
HEMORRHOIDAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	

HEMORRHOIDS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	8 / 298 (2.68%)	13 / 302 (4.30%)	
occurrences (all)	8	13	
ILEUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
INGUINAL HERNIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
LOSS OF DENTAL CROWN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
LOWER GASTROINTESTINAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
MUCOSITIS NOS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
MUCOSITIS ORAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	102 / 298 (34.23%)	41 / 302 (13.58%)	
occurrences (all)	127	51	
NAUSEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	106 / 298 (35.57%)	55 / 302 (18.21%)	
occurrences (all)	158	75	
DYSPEPSIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	7 / 298 (2.35%)	7 / 302 (2.32%)	
occurrences (all)	10	7	
ORAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	3 / 302 (0.99%)	
occurrences (all)	1	3	
PERIODONTAL DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	8 / 302 (2.65%)	
occurrences (all)	1	9	
PROCTITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
RECTAL FISTULA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	2	
RECTAL HEMORRHAGE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences (all)	3	0	
RECTAL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
SALIVARY DUCT INFLAMMATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
SIALORRHOEA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	

SMALL INTESTINAL MUCOSITIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	14 / 298 (4.70%)	4 / 302 (1.32%)	
occurrences (all)	20	4	
STOMACH PAIN alternative dictionary used: CTCAE 4			
subjects affected / exposed	11 / 298 (3.69%)	5 / 302 (1.66%)	
occurrences (all)	12	5	
TOOTH DAMAGE alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
TOOTHACHE alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	2 / 302 (0.66%)	
occurrences (all)	2	2	
TYPHLITIS alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences (all)	3	0	
UPPER GASTROINTESTINAL HEMORRHAGE alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	1 / 302 (0.33%)	
occurrences (all)	2	1	
VOMITING alternative dictionary used: CTCAE 4			
subjects affected / exposed	42 / 298 (14.09%)	22 / 302 (7.28%)	
occurrences (all)	61	26	
PAIN SWALLOWING alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			

CHOLECYSTITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences (all)	3	0	
HEPATIC INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
HEPATITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
HEPATITIS VIRAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
HEPATOMEGALY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
INGUINALE PUSTULE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PALMAR-PLANTAR ERYTHRODYSESTHESIA SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	10 / 298 (3.36%)	1 / 302 (0.33%)	
occurrences (all)	13	1	
HYPERHIDROSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
FOLLICULITIS			
alternative dictionary used: CTCAE			

4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
FISSURA ANI			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
EXANTHEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences (all)	4	0	
ERYTHRODERMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	2 / 302 (0.66%)	
occurrences (all)	5	2	
ERYTHEMA SKIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
ERYTHEMA MULTIFORME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	10 / 298 (3.36%)	3 / 302 (0.99%)	
occurrences (all)	16	3	
ERYTHEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
ECZEMA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
DRY SKIN			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	5 / 298 (1.68%)	1 / 302 (0.33%)	
occurrences (all)	5	1	
CUTANEOUS NODULES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
CELLULITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	3 / 302 (0.99%)	
occurrences (all)	1	3	
BULLOUS DERMATITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	3 / 302 (0.99%)	
occurrences (all)	1	4	
ALOPECIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	1 / 302 (0.33%)	
occurrences (all)	5	1	
INFLAMMATION OF THE SWEAT GLANDS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
PETECHIAE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PHYMOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
PRURITUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	13 / 298 (4.36%)	5 / 302 (1.66%)	
occurrences (all)	15	5	

PURPURA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	10 / 298 (3.36%)	9 / 302 (2.98%)	
occurrences (all)	11	12	
RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	3 / 302 (0.99%)	
occurrences (all)	5	3	
RASH ACNEIFORM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	1 / 302 (0.33%)	
occurrences (all)	3	1	
RASH MACULO-PAPULAR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	77 / 298 (25.84%)	30 / 302 (9.93%)	
occurrences (all)	104	34	
SKIN INDURATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
SKIN LESIONS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
SKIN ULCERATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	4 / 302 (1.32%)	
occurrences (all)	2	5	
STASIS DERMATITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
URTICARIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	3 / 298 (1.01%)	1 / 302 (0.33%)	
occurrences (all)	3	1	
VERRUCA SEBORRHOICA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
URINARY URGENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
URINARY TRACT PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	2 / 302 (0.66%)	
occurrences (all)	2	2	
URINARY RETENTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	8 / 298 (2.68%)	4 / 302 (1.32%)	
occurrences (all)	10	5	
URINARY INCONTINENCE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	2 / 302 (0.66%)	
occurrences (all)	4	2	
URINARY FREQUENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	5 / 302 (1.66%)	
occurrences (all)	0	6	
RENAL INSUFFICIENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
RENAL COLIC			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
RENAL CALCULI			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
HEMATURIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	2 / 302 (0.66%)	
occurrences (all)	6	2	
CYSTITIS NONINFECTIVE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	4 / 302 (1.32%)	
occurrences (all)	2	4	
CHRONIC KIDNEY DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
ACUTE KIDNEY INJURY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 298 (3.02%)	6 / 302 (1.99%)	
occurrences (all)	9	7	
Endocrine disorders			
HYPERPARATHYROIDISM			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
INCREASE OF CORTISOLURIA - HYPERPLASIA (LEFT SURRENAL)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
OSTEOPOROSIS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
PAIN (LEGS)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PAIN IN EXTREMITY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	3 / 302 (0.99%)	
occurrences (all)	6	3	
ARTHRALGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	10 / 302 (3.31%)	
occurrences (all)	3	11	
ARTHRITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	6 / 302 (1.99%)	
occurrences (all)	2	6	
BACK PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 298 (3.02%)	10 / 302 (3.31%)	
occurrences (all)	11	13	
BONE PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	9 / 302 (2.98%)	
occurrences (all)	4	12	
CHEST WALL PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences (all)	4	0	
DROP FOOT			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	

DUPUYTREN DISEASE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
FLANK PAIN			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	2	
GENERALIZED MUSCLE WEAKNESS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
JOINT EFFUSION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
JOINT RANGE OF MOTION DECREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
MUSCLE WEAKNESS LOWER LIMB			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences (all)	0	4	
MYALGIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	7 / 298 (2.35%)	12 / 302 (3.97%)	
occurrences (all)	7	12	
MYOSITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
NECK PAIN			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences (all)	0	3	
Infections and infestations			
INFECTION (FOCUS UNKNOWN)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	0 / 302 (0.00%)	
occurrences (all)	5	0	
ANGIO INVASIVE ASPERGILLOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
ANORECTAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	2 / 302 (0.66%)	
occurrences (all)	4	2	
BACTEREMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	33 / 298 (11.07%)	16 / 302 (5.30%)	
occurrences (all)	38	17	
BLADDER INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
BRONCHIAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	7 / 302 (2.32%)	
occurrences (all)	6	7	
CATHETER RELATED INFECTION			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	45 / 298 (15.10%)	15 / 302 (4.97%)	
occurrences (all)	54	15	
CHLAMYDIA PNEUMONIAE INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
CMV REACTIVATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	2 / 302 (0.66%)	
occurrences (all)	4	4	
COVID-19 INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
DEVICE RELATED INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
ENTEROCOCCUS FAECALIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
ENTEROCOLITIS INFECTIOUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	8 / 298 (2.68%)	3 / 302 (0.99%)	
occurrences (all)	9	3	
ESOPHAGEAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
EYE INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	2 / 302 (0.66%)	
occurrences (all)	3	2	

FUNGEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
GENERAL FUNGAL INFECTION (NO SEPSIS)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
GUM INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	2 / 302 (0.66%)	
occurrences (all)	1	2	
HERPES SIMPLEX VIRUS REACTIVATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
HHV6 INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
INFECTION ASPERGILLOSIS ON BAL			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
PLEURAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
INFECTION DUE TO NEUTROPENIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
INFECTION ENTEROCOCCO VANCOMIMICINE RESISTANT (VRE)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
INFECTION OTHER- GENERAL WITHOUT FOCUS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
INFECTION: OTHER: ACINETOBACTER			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
INFLUENZA, TYPE A			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
INVASIVE ASPERGILLOSIS PULMONAS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
JOINT INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
KIDNEY INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
LARYNGITIS			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
LIP INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	15 / 298 (5.03%)	17 / 302 (5.63%)	
occurrences (all)	15	18	
LUNG INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	62 / 298 (20.81%)	50 / 302 (16.56%)	
occurrences (all)	69	58	
LYMPH GLAND INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	3 / 302 (0.99%)	
occurrences (all)	2	3	
MUCOSAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	13 / 298 (4.36%)	12 / 302 (3.97%)	
occurrences (all)	17	13	
NAIL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
OTHER: HERPES			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
OTITIS EXTERNA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
PAPULOPUSTULAR RASH			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	11 / 298 (3.69%)	2 / 302 (0.66%)	
occurrences (all)	13	2	

PARAINFLUENZA (NO SPECIFIC CLINICAL SITE OF INFECTION)			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
PARONYCHIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
PENILE INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	3 / 302 (0.99%)	
occurrences (all)	2	3	
PHARYNGITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	3 / 302 (0.99%)	
occurrences (all)	3	3	
PHLEBITIS INFECTIVE			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	2 / 302 (0.66%)	
occurrences (all)	2	2	
INFECTION CMV			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
PROSTATE INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
RASH PUSTULAR			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	4 / 298 (1.34%)	4 / 302 (1.32%)	
occurrences (all)	5	4	
RHINITIS INFECTIVE			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 298 (0.00%)	3 / 302 (0.99%)	
occurrences (all)	0	3	
SEPSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	21 / 298 (7.05%)	9 / 302 (2.98%)	
occurrences (all)	25	13	
SEPTIC SHOCK			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
SINUSITIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	5 / 302 (1.66%)	
occurrences (all)	1	5	
SKIN INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	17 / 298 (5.70%)	16 / 302 (5.30%)	
occurrences (all)	20	16	
SMALL INTESTINE INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences (all)	3	0	
SOFT TISSUE INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	3 / 302 (0.99%)	
occurrences (all)	1	3	
SYSTEMIC VIRAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
TOOTH INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	6 / 302 (1.99%)	
occurrences (all)	3	6	

UPPER RESPIRATORY INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	10 / 298 (3.36%)	12 / 302 (3.97%)	
occurrences (all)	10	15	
URETHRAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	3	0	
URINARY TRACT INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	16 / 298 (5.37%)	15 / 302 (4.97%)	
occurrences (all)	19	18	
VAGINAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
VIREMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
VULVAL INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
WOUND INFECTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	2	0	
Metabolism and nutrition disorders			
HYPOMAGNESEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	5 / 302 (1.66%)	
occurrences (all)	10	6	
VITAMIN B12 DEFICIENCY			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
HYPOCALCEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	6 / 298 (2.01%)	6 / 302 (1.99%)	
occurrences (all)	6	7	
HYPOALBUMINEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	7 / 302 (2.32%)	
occurrences (all)	5	10	
HYPERURICEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	6 / 298 (2.01%)	4 / 302 (1.32%)	
occurrences (all)	8	5	
HYPERNATREMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	0 / 302 (0.00%)	
occurrences (all)	3	0	
HYPERMAGNESEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	
HYPERKALEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	2 / 298 (0.67%)	8 / 302 (2.65%)	
occurrences (all)	2	9	
HYPERGLYCEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	9 / 298 (3.02%)	2 / 302 (0.66%)	
occurrences (all)	10	2	
FLUID RETENTION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	0 / 302 (0.00%)	
occurrences (all)	1	0	

DEHYDRATION			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	2 / 302 (0.66%)	
occurrences (all)	0	2	
CHLORIDE INCREASED			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
B12 AND FOLIC ACID DEFICIENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	
ANOREXIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	39 / 298 (13.09%)	25 / 302 (8.28%)	
occurrences (all)	48	32	
ALKALOSIS			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	1 / 298 (0.34%)	1 / 302 (0.33%)	
occurrences (all)	1	1	
TUMOR LYSIS SYNDROME			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	3 / 298 (1.01%)	1 / 302 (0.33%)	
occurrences (all)	3	1	
HYPOPHOSPHATEMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	5 / 298 (1.68%)	5 / 302 (1.66%)	
occurrences (all)	6	6	
HYPONATREMIA			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	18 / 298 (6.04%)	8 / 302 (2.65%)	
occurrences (all)	37	14	
HYPOKALEMIA			
alternative dictionary used: CTCAE 4			

subjects affected / exposed	46 / 298 (15.44%)	39 / 302 (12.91%)	
occurrences (all)	74	69	
VITAMIN D DEFICIENCY			
alternative dictionary used: CTCAE 4			
subjects affected / exposed	0 / 298 (0.00%)	1 / 302 (0.33%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The futility analysis indicated futility. However, the IDMC recommended the study to continue as planned taking into account the risk-benefit for the patients. Since futility had already been concluded, the final analysis was descriptive.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/37914482