Clinical trial results:
High Risk Neuroblastoma Study 1 of SIOP-Europe (SIOPEN)

Summary

EudraCT number	2006-001489-17
Trial protocol	AT ES GB BE DK IT IE HU FI SI PL GR
Global end of trial date	30 January 2025

Results information

Result version number	v1 (current)
This version publication date	25 April 2026
First version publication date	25 April 2026
Summary attachment (see zip file)	HR-NBL1_SIOPEN_Public Lay Summary (HR-NBL1_SIOPEN_Public_Lay_Summary_30.03.2026.pdf)

Trial information

Trial identification

Sponsor protocol code	SIOPENRNET003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01704716
WHO universal trial number (UTN)	-
Other trial identifiers	HR-NBL1 (SIOPEN): HR-NBL1

Notes:

Sponsors

Sponsor organisation name	St. Anna Kinderkrebsforschung
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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	15 September 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 January 2025
Global end of trial reached?	Yes
Global end of trial date	30 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1) R0 randomisation (2002-2005) found significantly improved treatment tolerance with prophylactic use of G-CSF during Rapid COJEC Induction: new standard of care.
2) R1 rand. (2002-2010) found signif. superiority for MAT with busulfan and melphalan (BuMel) over MAT with carboplatin, etoposide and melphalan (CEM). BuMel: new standard MAT.
3) R2 rand. comparing short-term infusion (STI) ch14.18/CHO vs. STI ch14.18/CHO + scIL2 (2006-2013) found subst. higher toxicity profile in arm with scIL2, but no survival benefit (neither EFS, nor OS).
4) R3 rand. compared Rapid COJEC vs. the modified N7 regimen (2011-2017): no outcome differ. (neither EFS nor OS) detected but more favourable toxic. profile: Rapid COJEC confirmed standard Induction regimen.
5) R4 rand. altered the duration of inf. time to 10 days ctn LTI ch14.18/CHO (same total dose) vs. LTI ch14.18/CHO + scIL2; (2014-2018): no dif. in EFS or OS, but more favourable tox. prof. without scIL2: new immunother. standard maintenance.

Protection of trial subjects:

Detailed in the Study Protocol under: B. General Principles, page 252-253:
9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.
10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
All vulnerable groups and individuals should receive specifically considered protection.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 March 2002
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Scientific research
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 27
Country: Number of subjects enrolled	Austria: 135
Country: Number of subjects enrolled	Belgium: 128
Country: Number of subjects enrolled	Czechia: 67

Country: Number of subjects enrolled	Denmark: 40
Country: Number of subjects enrolled	Finland: 20
Country: Number of subjects enrolled	France: 701
Country: Number of subjects enrolled	Greece: 74
Country: Number of subjects enrolled	Hong Kong: 29
Country: Number of subjects enrolled	Hungary: 29
Country: Number of subjects enrolled	Ireland: 30
Country: Number of subjects enrolled	Israel: 198
Country: Number of subjects enrolled	Italy: 636
Country: Number of subjects enrolled	New Zealand: 1
Country: Number of subjects enrolled	Norway: 53
Country: Number of subjects enrolled	Poland: 170
Country: Number of subjects enrolled	Portugal: 17
Country: Number of subjects enrolled	Slovakia: 29
Country: Number of subjects enrolled	Slovenia: 12
Country: Number of subjects enrolled	Spain: 380
Country: Number of subjects enrolled	Sweden: 78
Country: Number of subjects enrolled	Switzerland: 45
Country: Number of subjects enrolled	United Kingdom: 678
Worldwide total number of subjects	3577
EEA total number of subjects	2599

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	6
Infants and toddlers (28 days-23 months)	993
Children (2-11 years)	2488
Adolescents (12-17 years)	81
Adults (18-64 years)	9
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

FPFV (first patient in): 23-Apr-2002
LPFV (last patient in): 14-Jun-2023
LPLV (last patient out): 30-Jan-2025
End of global recruitment: 31-Jul-2023
Total number of patients recruited: 3569
Number of recruiting countries: 23
Number of sites with recruited patients: 188

Pre-assignment

Screening details:

Pre-registration is only possible if the eligibility criteria are met.
Registration will be final once the disease description at diagnosis including MYCN results is complete.

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	BUMEL (Cohort R1)

Arm description:

BUMEL - busulfan and melphalan

Arm type	Experimental
Investigational medicinal product name	Busulfan
Investigational medicinal product code	ATC code: L01AB01
Other name	Busilvex, Busulphan, Myleran
Pharmaceutical forms	Solution for infusion, Tablet
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

The BuMel MAT regimen consists of oral administration of busulphan and the short i.v. infusion of melphalan. In July 2007 (Amendment 3) oral busulfan was changed to i.v. busulfan (Busilvex).
Oral busulfan is given at 37.5 mg/m²/dose every 6 hours for a total of 16 doses over 4 consecutive days (total 600 mg/m²).
Intravenous administration of busulfan (Busilvex) consists of a two-hour infusion every 6 hours over 4 (or 5) consecutive days through a central venous catheter only with dosage according to BW:
< 9 kg: 1.0 mg/kg
9 kg to < 16 kg: 1.2 mg/kg
16 kg to 23 kg: 1.1 mg/kg
>23 kg to 34 kg: 0.95 mg/kg
>34 kg: 0.8 mg/kg

Investigational medicinal product name	Melphalan
Investigational medicinal product code	HS Code: 3004.90
Other name	Alkeran
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Injection

Dosage and administration details:

In case of body weight below 12 kg the melphalan dose calculation is recommended to be dosed by kg/BW, i.e. 4 mg/kg. For infants with a weight ≤ 5 kg, a further 1/3 reduction is advised.
Short i.v. infusion.

Arm title	CEM (Cohort R1)

Arm description: CEM - MAT carboplatin, etoposide, and melphalan	
Arm type	Active comparator
Investigational medicinal product name	Carboplatin
Investigational medicinal product code	ATC Code: LO1X A02
Other name	Paraplatin
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Dose (mg) = target AUC (mg/ml x min) x [GFR ml/min + 25]	
Investigational medicinal product name	Etoposide
Investigational medicinal product code	ATC code: L01CB01
Other name	VP16
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use
Dosage and administration details: 350 mg/m²/course	
Investigational medicinal product name	Melphalan
Investigational medicinal product code	ATC code: L01AA03
Other name	Alkeran
Pharmaceutical forms	Powder for injection
Routes of administration	Intravenous use
Dosage and administration details: 210 mg/m²/course	
Arm title	STI ch14.18/CHO (Cohort R2)
Arm description: anti-GD2 antibody ch14.18/CHO (Dinutuximab beta)	
Arm type	Active comparator
Investigational medicinal product name	ch14.18/CHO antibody
Investigational medicinal product code	NA
Other name	Chimeric 14.18 anti-GD2 monoclonal antibody, Dinutuximab beta, Qarziba
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: ch14.18/CHO is given at a dose of 20 mg/m²/day over five days every four weeks for five courses.	
Arm title	STI ch14.18/CHO + scIL-2 (Cohort R2)
Arm description: anti-GD2 antibody ch14.18/CHO (Dinutuximab beta) and subcutaneous IL-2	
Arm type	Experimental
Investigational medicinal product name	ch14.18/CHO antibody
Investigational medicinal product code	NA
Other name	Chimeric 14.18 anti-GD2 monoclonal antibody, Dinutuximab beta, Qarziba
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: ch14.18/CHO is given at a dose of 20 mg/m²/day over five days every four weeks for five courses.	
Investigational medicinal product name	Aldesleukin
Investigational medicinal product code	ATC code: L03AC01
Other name	Interleukin 2, IL-2, IL2, Proleukin
Pharmaceutical forms	Powder for solution for injection

Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

3-18 × 10 IU/m²/day continuous i.v. infusion for 4–5 days.

Arm title	COJEC (Cohort R3)

Arm description:

Rapid COJEC (rCOJEC; cisplatin [C], vincristine [O], carboplatin [J], etoposide [E], and cyclophosphamide [C])

Arm type	Active comparator
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	ATC Code: L01XA01
Other name	CDDP
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

80 mg/m²/24 hours.
In case of body weight below 12 kg the dose of 2.666 mg/kg. For infants with a weight < or equal to 5 kg, a further 1/3 reduction is advised.

Investigational medicinal product name	Vincristine
Investigational medicinal product code	ATC code: L01CA02
Other name	VCR
Pharmaceutical forms	Solution for injection
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

1.5 mg/m² (maximum dose 2 mg) as a single i.v. bolus.
In case of body weight below 12 kg the dose of 0.05 mg/kg.

Investigational medicinal product name	Carboplatin
Investigational medicinal product code	ATC Code: LO1X A02
Other name	CBDCA, Paraplatin
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Dose (mg) = target AUC (mg/ml x min) x [GFR ml/min + 25].

Investigational medicinal product name	Etoposide
Investigational medicinal product code	ATC code: L01CB01
Other name	VP16
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

350 mg/m²/course

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	ATC code: L01AA01
Other name	CYC, Endoxan
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

2.1 g/m²/course

Arm title	N7 (Cohort R3)

Arm description:

Memorial Sloan Kettering Cancer Center (MSKCC) N5 induction regimen (MSKCC-N5)

Arm type	Experimental

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	ATC Code: L01XA01
Other name	CDDP
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

80 mg/m²/24 hours.
In case of body weight below 12 kg the dose of 2.666 mg/kg. For infants with a weight < or equal to 5 kg, a further 1/3 reduction is advised.

Investigational medicinal product name	Vincristine
Investigational medicinal product code	ATC code: L01CA02
Other name	VCR
Pharmaceutical forms	Solution for injection
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

1.5 mg/m² (maximum dose 2 mg) as a single i.v. bolus.
In case of body weight below 12 kg the dose of 0.05 mg/kg.

Investigational medicinal product name	Doxorubicin
Investigational medicinal product code	ATC code: L01DB01
Other name	DOXO, Adriamycin
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use, Intravesical use

Dosage and administration details:

22.5 mg/m²/day in a 48-hour continuous infusion. Infants and children with a body weight below 12 kg should be dosed according to their weight in kg instead of their body surface area (m²) according to the known formula of 30 kg = 1 m². Doxorubicin: 0.75 mg/kg/day.

Investigational medicinal product name	Etoposide
Investigational medicinal product code	ATC code: L01CB01
Other name	VP16
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

350 mg/m²/course.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	ATC code: L01AA01
Other name	CYC, Endoxan
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

2.1 g/m²/course.

Arm title	Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)

Arm description:

Cont. infusion of ch14.18/CHO and oral 13-cis-retinoic acid (RA)

Arm type	Active comparator
Investigational medicinal product name	ch14.18/CHO antibody
Investigational medicinal product code	NA
Other name	Chimeric 14.18 anti-GD2 monoclonal antibody, Dinutuximab beta, Qarziba
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

ch14.18/CHO is given at a dose of 20 mg/m²/day over five days every four weeks for five courses.

Investigational medicinal product name	Isotretinoin
Investigational medicinal product code	ATC code: D10BA01
Other name	13-cis-retinoic acid, 13-cis-RA, Roaccutan
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Patients will receive isotretinoin (13-cis-RA) 160 mg/m²/day divided into two equal doses given orally twice a day for 14 days after the completion of the ch14.18/CHO infusion.
The starting day is dependent on the duration of ch14.18/CHO infusion and may be either day 19, 23, 24 or 30.

Arm title	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4)

Arm description:

Cont. infusion of ch14.18/CHO + scIL-2

Arm type	Experimental
Investigational medicinal product name	ch14.18/CHO antibody
Investigational medicinal product code	NA
Other name	Chimeric 14.18 anti-GD2 monoclonal antibody, Dinutuximab beta, Qarziba
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

ch14.18/CHO is given at a dose of 20 mg/m²/day over five days every four weeks for five courses.

Investigational medicinal product name	Aldesleukin
Investigational medicinal product code	ATC code: L03AC01
Other name	Interleukin 2, IL-2, IL2, Proleukin
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

3-18 × 10 IU/m²/day continuous i.v. infusion for 4–5 days.

Arm title	PPGCSF (Cohort R0)

Arm description:

Primary prophylactic (PP) use of granulocyte colony-stimulating factor (G-CSF) during COJEC

Arm type	Experimental
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	ATC Code: L01XA01
Other name	CDDP
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

80 mg/m²/24 hours.
In case of body weight below 12 kg the dose of 2.666 mg/kg. For infants with a weight < or equal to 5 kg, a further 1/3 reduction is advised.

Investigational medicinal product name	Vincristine
Investigational medicinal product code	ATC code: L01CA02
Other name	VCR
Pharmaceutical forms	Solution for injection
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

1.5 mg/m² (maximum dose 2 mg) as a single i.v. bolus.
In case of body weight below 12 kg the dose of 0.05 mg/kg.

Investigational medicinal product name	Carboplatin
Investigational medicinal product code	ATC Code: LO1X A02
Other name	CBDCA, Paraplatin

Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Dose (mg) = target AUC (mg/ml x min) x [GFR ml/min + 25]

Investigational medicinal product name	Etoposide
Investigational medicinal product code	ATC code: L01CB01
Other name	VP16
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

350 mg/m²/course

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	ATC code: L01AA01
Other name	CYC, Endoxan
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

2.1 g/m²/course

Investigational medicinal product name	G-CSF
Investigational medicinal product code	ATC code: L03AA
Other name	Filgrastim, Nivestim, Filgrastim HEXAL, NEUPOGEN, NEULASTA, ACCOFIL
Pharmaceutical forms	Concentrate for solution for injection, Solution for infusion, Solution for injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

A single daily subcutaneous injection of 10 microgram/kg/day for 5 days, beginning at least 24 hours after the last chemotherapy dose.

Arm title	STGCSF (Cohort R0)

Arm description:

Control Arm with symptom-triggered granulocyte colony-stimulating factor (ST G-CSF) during COJEC

Arm type	Active comparator
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	ATC Code: L01XA01
Other name	CDDP
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

80 mg/m²/24 hours.
In case of body weight below 12 kg the dose of 2.666 mg/kg. For infants with a weight < or equal to 5 kg, a further 1/3 reduction is advised.

Investigational medicinal product name	Vincristine
Investigational medicinal product code	ATC code: L01CA02
Other name	VCR
Pharmaceutical forms	Solution for injection
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

1.5 mg/m² (maximum dose 2 mg) as a single i.v. bolus.
In case of body weight below 12 kg the dose of 0.05 mg/kg.

Investigational medicinal product name	Carboplatin
Investigational medicinal product code	ATC Code: LO1X A02
Other name	CBDCA, Paraplatin
Pharmaceutical forms	Solution for infusion

Routes of administration	Intravenous use
Dosage and administration details: Dose (mg) = target AUC (mg/ml x min) x [GFR ml/min + 25]	
Investigational medicinal product name	Etoposide
Investigational medicinal product code	ATC code: L01CB01
Other name	VP16
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Infusion , Intravenous use
Dosage and administration details: 350 mg/m²/course.	
Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	ATC code: L01AA01
Other name	CYC, Endoxan
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use
Dosage and administration details: 2.1 g/m²/course	
Arm title	Observational Cohort
Arm description: Non-randomised Standard of Care (observational cohort)	
Arm type	Standard of care
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	BUMEL (Cohort R1)	CEM (Cohort R1)	STI ch14.18/CHO (Cohort R2)
Started	296	302	200
Completed	292	278	160
Not completed	4	24	40
Adverse event, serious fatal	-	-	-
change to COJEC	-	-	-
Physician decision	-	-	-
Toxicity	-	-	-
stopped immunotherapy	-	-	21
poor response	-	-	-
Adverse event, non-fatal	-	-	-
did not received dinutuximab beta	-	-	12
GD2 or IL2 not given	-	-	-
change to other treatment	-	-	-
disease progression	-	5	-
change to N 7	-	-	-
not received N7	-	-	-
Toxicity -death	-	-	-
GD2 not given	-	-	-

interrupted immunotherapy	-	-	3
parental decision	-	-	-
received busulfan and melphalan	-	18	-
Death- progression of disease	-	-	-
not received COJEC	-	-	-
received carboplatin, etoposide and melphalan	3	-	-
did not received IL2	-	-	-
Complications	-	-	-
incomplete therapy data	-	-	4
unknown	-	-	-
Decision to surgery	-	-	-
disease progression before	1	-	-
stopped or interrupted therapy	-	-	-
Lost to follow-up	-	1	-
Lack of efficacy	-	-	-

Number of subjects in period 1	STI ch14.18/CHO + scIL-2 (Cohort R2)	COJEC (Cohort R3)	N7 (Cohort R3)
Started	206	313	317
Completed	118	288	292
Not completed	88	25	25
Adverse event, serious fatal	-	-	2
change to COJEC	-	-	4
Physician decision	-	-	-
Toxicity	-	6	-
stopped immunotherapy	57	-	-
poor response	-	-	-
Adverse event, non-fatal	-	-	7
did not received dinutuximab beta	11	-	-
GD2 or IL2 not given	-	-	-
change to other treatment	-	6	-
disease progression	-	-	3
change to N 7	-	1	-
not received N7	-	-	4
Toxicity -death	-	-	-
GD2 not given	-	-	-
interrupted immunotherapy	13	-	-
parental decision	-	-	-
received busulfan and melphalan	-	-	-
Death- progression of disease	-	-	-

not received COJEC	-	2	-
received carboplatin, etoposide and melphalan	-	-	-
did not received IL2	3	-	-
Complications	-	-	-
incomplete therapy data	4	9	-
unknown	-	-	3
Decision to surgery	-	-	2
disease progression before	-	-	-
stopped or interrupted therapy	-	-	-
Lost to follow-up	-	-	-
Lack of efficacy	-	1	-

Number of subjects in period 1	Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4)	PPGCSF (Cohort R0)
Started	205	202	119
Completed	162	129	110
Not completed	43	73	9
Adverse event, serious fatal	-	-	-
change to COJEC	-	-	-
Physician decision	1	-	-
Toxicity	-	-	3
stopped immunotherapy	-	-	-
poor response	-	-	2
Adverse event, non-fatal	8	-	-
did not received dinutuximab beta	-	-	-
GD2 or IL2 not given	-	13	-
change to other treatment	-	-	-
disease progression	19	-	-
change to N 7	-	-	-
not received N7	-	-	-
Toxicity -death	-	-	1
GD2 not given	4	-	-
interrupted immunotherapy	-	-	-
parental decision	-	-	-
received busulfan and melphalan	-	-	-
Death- progression of disease	-	-	3
not received COJEC	-	-	-
received carboplatin, etoposide and melphalan	-	-	-
did not received IL2	-	-	-

Complications	2	-	-
incomplete therapy data	8	16	-
unknown	1	-	-
Decision to surgery	-	-	-
disease progression before	-	-	-
stopped or interrupted therapy	-	44	-
Lost to follow-up	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	STGCSF (Cohort R0)	Observational Cohort
Started	120	1710
Completed	114	1710
Not completed	6	0
Adverse event, serious fatal	-	-
change to COJEC	-	-
Physician decision	-	-
Toxicity	1	-
stopped immunotherapy	-	-
poor response	2	-
Adverse event, non-fatal	-	-
did not received dinutuximab beta	-	-
GD2 or IL2 not given	-	-
change to other treatment	-	-
disease progression	-	-
change to N 7	-	-
not received N7	-	-
Toxicity -death	-	-
GD2 not given	-	-
interrupted immunotherapy	-	-
parental decision	1	-
received busulfan and melphalan	-	-
Death- progression of disease	-	-
not received COJEC	-	-
received carboplatin, etoposide and melphalan	-	-
did not received IL2	-	-
Complications	2	-
incomplete therapy data	-	-
unknown	-	-
Decision to surgery	-	-

disease progression before	-	-
stopped or interrupted therapy	-	-
Lost to follow-up	-	-
Lack of efficacy	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Total Study Period
Reporting group description:	
HR-NBL1 Study Period: 02.02.2002 - 30.1.2025	

Reporting group values	Total Study Period	Total	
Number of subjects	3577	3577	
Age categorical			
Age categorical			
Units: Subjects			
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	6	6	
Infants and toddlers (28 days-23 months)	993	993	
Children (2-11 years)	2488	2488	
Adolescents (12-17 years)	81	81	
Adults (18-64 years)	9	9	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Age continuous			
Units: years			
median	2.92		
standard deviation	± 2.8	-	
Gender categorical			
Gender			
Units: Subjects			
Female	1515	1515	
Male	2062	2062	

End points

End points reporting groups

Reporting group title	BUMEL (Cohort R1)
Reporting group description:	
BUMEL - busulfan and melphalan	
Reporting group title	CEM (Cohort R1)
Reporting group description:	
CEM - MAT carboplatin, etoposide, and melphalan	
Reporting group title	STI ch14.18/CHO (Cohort R2)
Reporting group description:	
anti-GD2 antibody ch14.18/CHO (Dinutuximab beta)	
Reporting group title	STI ch14.18/CHO + scIL-2 (Cohort R2)
Reporting group description:	
anti-GD2 antibody ch14.18/CHO (Dinutuximab beta) and subcutaneous IL-2	
Reporting group title	COJEC (Cohort R3)
Reporting group description:	
Rapid COJEC (rCOJEC; cisplatin [C], vincristine [O], carboplatin [J], etoposide [E], and cyclophosphamide [C])	
Reporting group title	N7 (Cohort R3)
Reporting group description:	
Memorial Sloan Kettering Cancer Center (MSKCC) N5 induction regimen (MSKCC-N5)	
Reporting group title	Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)
Reporting group description:	
Cont. infusion of ch14.18/CHO and oral 13-cis-retinoic acid (RA)	
Reporting group title	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4)
Reporting group description:	
Cont. infusion of ch14.18/CHO + scIL-2	
Reporting group title	PPGCSF (Cohort R0)
Reporting group description:	
Primary prophylactic (PP) use of granulocyte colony-stimulating factor (G-CSF) during COJEC	
Reporting group title	STGCSF (Cohort R0)
Reporting group description:	
Control Arm with symptom-triggered granulocyte colony-stimulating factor (ST G-CSF) during COJEC	
Reporting group title	Observational Cohort
Reporting group description:	
Non-randomised Standard of Care (observational cohort)	

Primary: 3-years Event-free survival - EFS

End point title	3-years Event-free survival - EFS[1]
End point description:	
End point type	Primary
End point timeframe:	
3 years	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This study had a total of 5 randomizations. Endpoints were predefined on a cohort-specific

basis in accordance with the scientific objectives of each cohort. As a result, not all endpoints are applicable to every study arm. This endpoint EFS is designated as the primary endpoint for cohorts R1, R2, R3, R4.

End point values	BUMEL (Cohort R1)	CEM (Cohort R1)	STI ch14.18/CHO (Cohort R2)	STI ch14.18/CHO + scIL-2 (Cohort R2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	296	301[2]	200	206
Units: Patients	296	302	200	206

Notes:

[2] - No follow-up information was reported for one patient

End point values	COJEC (Cohort R3)	N7 (Cohort R3)	Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	312[3]	314[4]	205	200[5]
Units: Patients	313	317	205	202

Notes:

[3] - No follow-up information was reported for one patient

[4] - No follow-up information was reported for three patients

[5] - No follow-up information was reported for two patients

Statistical analyses

Statistical analysis title	EFS Comparison Cohort R1

Statistical analysis description:

high-dose chemotherapy with busulfan and melphalan (BUMEL) compared with carboplatin, etoposide, and melphalan (CEM)

Comparison groups	BUMEL (Cohort R1) v CEM (Cohort R1)
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.713
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.582
upper limit	0.873

Statistical analysis title	EFS Comparison Cohort R2

Statistical analysis description:

STI ch14.18/CHO (dinutuximab beta) and subcutaneous IL-2 compared with dinutuximab beta alone

Comparison groups	STI ch14.18/CHO + scIL-2 (Cohort R2) v STI ch14.18/CHO (Cohort R2)

Number of subjects included in analysis	406
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.457
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.897
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.673
upper limit	1.195

Statistical analysis title	EFS Comparison Cohort R3
Statistical analysis description: difference in efficacy between MSKCC-N5 and rCOJEC: modified N7 vs Rapid COJEC	
Comparison groups	N7 (Cohort R3) v COJEC (Cohort R3)
Number of subjects included in analysis	626
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.277
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.892
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.727
upper limit	1.096

Statistical analysis title	EFS Comparison Cohort R4
Statistical analysis description: continuous infusion of LTI ch14.18/CHO ± aldesleukin (IL-2): LTI ch14.18/CHO + scIL-2 vs LTI ch14.18/CHO	
Comparison groups	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4) v Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)
Number of subjects included in analysis	405
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.825
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.966

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.707
upper limit	1.318

Secondary: 3-years Overall survival - OS

End point title	3-years Overall survival - OS[6]

End point description:

End point type	Secondary

End point timeframe:

3 years

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This study had a total of 5 randomizations. Endpoints were predefined on a cohort-specific basis in accordance with the scientific objectives of each cohort. As a result, not all endpoints are applicable to every study arm. This endpoint OS is designated as the primary endpoint for cohorts R1, R2, R3, R4.

End point values	BUMEL (Cohort R1)	CEM (Cohort R1)	STI ch14.18/CHO (Cohort R2)	STI ch14.18/CHO + scIL-2 (Cohort R2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	296	301[7]	200	206
Units: Patients	296	302	200	206

Notes:

[7] - No follow-up information was reported for one patient

End point values	COJEC (Cohort R3)	N7 (Cohort R3)	Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	312[8]	314[9]	205	200[10]
Units: Patients	313	317	205	202

Notes:

[8] - No follow-up information was reported for one patient

[9] - No follow-up information was reported for three patients

[10] - No follow-up information was reported for two patients

Statistical analyses

Statistical analysis title	OS Comparison Cohort R1

Statistical analysis description:

high-dose chemotherapy with busulfan and melphalan (BUMEL) compared with carboplatin, etoposide, and melphalan (CEM)

Comparison groups	BUMEL (Cohort R1) v CEM (Cohort R1)

Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.714
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.579
upper limit	0.882

Statistical analysis title	OS Comparison Cohort R2
Statistical analysis description:	
ch14.18/CHO (dinutuximab beta) and subcutaneous IL-2 compared with dinutuximab beta alone	
Comparison groups	STI ch14.18/CHO + scIL-2 (Cohort R2) v STI ch14.18/CHO (Cohort R2)
Number of subjects included in analysis	406
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.972
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.995
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.355

Statistical analysis title	OS Comparison Cohort R3
Statistical analysis description:	
difference in efficacy between MSKCC-N5 and rCOJEC: modified N7 vs Rapid COJEC	
Comparison groups	N7 (Cohort R3) v COJEC (Cohort R3)
Number of subjects included in analysis	626
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.113
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.832
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.664
upper limit	1.044

Statistical analysis title	OS Comparison Cohort R4
Statistical analysis description:	
continuous infusion of ch14.18/CHO + retinoic acid (RA) ± aldesleukin (IL-2): LTI ch14.18/CHO + scIL-2 vs LTI ch14.18/CHO	
Comparison groups	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4) v Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)
Number of subjects included in analysis	405
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.536
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.897
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.637
upper limit	1.265

Secondary: 3-years Cumulative incidence of relapse - CIR

End point title	3-years Cumulative incidence of relapse - CIR[11]
End point description:	
End point type	Secondary
End point timeframe:	
3 years	

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This study had a total of 5 randomizations. Endpoints were predefined on a cohort-specific basis in accordance with the scientific objectives of each cohort. As a result, not all endpoints are applicable to every study arm. This endpoint CIR is designated as the primary endpoint for cohorts R1, R2, R3, R4.

End point values	BUMEL (Cohort R1)	CEM (Cohort R1)	STI ch14.18/CHO (Cohort R2)	STI ch14.18/CHO + scIL-2 (Cohort R2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	296	301[12]	200	206
Units: Patients	296	302	200	206

Notes:

[12] - No follow-up information was reported for one patient

End point values	COJEC (Cohort R3)	N7 (Cohort R3)	Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2

				(Cohort R4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	312[13]	314[14]	205	200[15]
Units: Patients	313	317	205	202

Notes:

[13] - No follow-up information was reported for one patient

[14] - No follow-up information was reported for three patients

[15] - No follow-up information was reported for two patients

Statistical analyses

Statistical analysis title	CIR Comparison Cohort R1
Statistical analysis description:	
high-dose chemotherapy with busulfan and melphalan (BUMEL) compared with carboplatin, etoposide, and melphalan (CEM)	
Comparison groups	BUMEL (Cohort R1) v CEM (Cohort R1)
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.753
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	0.93

Statistical analysis title	CIR Comparison Cohort R2
Statistical analysis description:	
STI ch14.18/CHO (dinutuximab beta) and subcutaneous IL-2 compared with dinutuximab beta alone	
Comparison groups	STI ch14.18/CHO (Cohort R2) v STI ch14.18/CHO + scIL-2 (Cohort R2)
Number of subjects included in analysis	406
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.934
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.695
upper limit	1.254

Statistical analysis title	CIR Comparison Cohort R3
Statistical analysis description: difference in efficacy between MSKCC-N5 and rCOJEC: modified N7 vs Rapid COJEC	
Comparison groups	N7 (Cohort R3) v COJEC (Cohort R3)
Number of subjects included in analysis	626
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.206
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.867
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.694
upper limit	1.082

Statistical analysis title	CIR Comparison Cohort R4
Statistical analysis description: Retinoic acid (RA) + continuous infusion of ch14.18/CHO ± aldesleukin (IL-2): RA + LTI ch14.18/CHO + scIL-2 vs LTI ch14.18/CHO	
Comparison groups	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4) v Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)
Number of subjects included in analysis	405
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.426
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.875
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.629
upper limit	1.216

Secondary: 3-years Non-relapse mortality - NRM

End point title	3-years Non-relapse mortality - NRM[16]
End point description:	

End point type	Secondary
End point timeframe: 3 years	

Notes:

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

Justification: This study had a total of 5 randomizations. Endpoints were predefined on a cohort-specific basis in accordance with the scientific objectives of each cohort. As a result, not all endpoints are applicable to every study arm. This endpoint NRM is designated as the primary endpoint for cohorts R1, R2, R3, R4.

End point values	BUMEL (Cohort R1)	CEM (Cohort R1)	STI ch14.18/CHO (Cohort R2)	STI ch14.18/CHO + scIL-2 (Cohort R2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	296	301[17]	200	206
Units: Patients	296	302	200	206

Notes:

[17] - No follow-up information was reported for one patient

End point values	COJEC (Cohort R3)	N7 (Cohort R3)	Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	312[18]	314[19]	205	200[20]
Units: Patients	313	317	205	202

Notes:

[18] - No follow-up information was reported for one patient

[19] - No follow-up information was reported for three patients

[20] - No follow-up information was reported for two patients

Statistical analyses

Statistical analysis title	NRM Comparison Cohort R1

Statistical analysis description:

high-dose chemotherapy with busulfan and melphalan (BUMEL) compared with carboplatin, etoposide, and melphalan (CEM)

Comparison groups	BUMEL (Cohort R1) v CEM (Cohort R1)
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.045
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.409
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	0.982

Statistical analysis title	NRM Comparison Cohort R2

Statistical analysis description:

STI ch14.18/CHO (dinutuximab beta) and subcutaneous IL-2 compared with dinutuximab beta alone

Comparison groups	STI ch14.18/CHO + scIL-2 (Cohort R2) v STI ch14.18/CHO

	(Cohort R2)
Number of subjects included in analysis	406
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.456
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.139
upper limit	2.423

Statistical analysis title	NRM Comparison Cohort R3
Statistical analysis description: difference in efficacy between MSKCC-N5 and rCOJEC: modified N7 vs Rapid COJEC	
Comparison groups	N7 (Cohort R3) v COJEC (Cohort R3)
Number of subjects included in analysis	626
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.408
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	1.279
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.714
upper limit	2.288

Statistical analysis title	NRM Comparison Cohort R4
Statistical analysis description: Retinoic acid (RA) + continuous infusion of ch14.18/CHO ± aldesleukin (IL-2): RA + LTI ch14.18/CHO + scIL-2 vs LTI ch14.18/CHO	
Comparison groups	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4) v Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)
Number of subjects included in analysis	405
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.133
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	2.771

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.734
upper limit	10.462

Secondary: 3-years Cumulative incidence of secondary malignancies

End point title	3-years Cumulative incidence of secondary malignancies[21]

End point description:

End point type	Secondary

End point timeframe:

3 years

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This study had a total of 5 randomizations. Endpoints were predefined on a cohort-specific basis in accordance with the scientific objectives of each cohort. As a result, not all endpoints are applicable to every study arm. This endpoint is designated as the primary endpoint for cohorts R1, R2, R3, R4.

End point values	BUMEL (Cohort R1)	CEM (Cohort R1)	STI ch14.18/CHO (Cohort R2)	STI ch14.18/CHO + scIL-2 (Cohort R2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	296	301[22]	200	206
Units: Patients	296	302	200	206

Notes:

[22] - No follow-up information was reported for one patient

End point values	COJEC (Cohort R3)	N7 (Cohort R3)	Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	312[23]	314[24]	205	200[25]
Units: Patients	313	317	205	202

Notes:

[23] - No follow-up information was reported for one patient

[24] - No follow-up information was reported for three patients

[25] - No follow-up information was reported for two patients

Statistical analyses

Statistical analysis title	Comparison of CI of sec. malignancies Cohort R1

Statistical analysis description:

high-dose chemotherapy with busulfan and melphalan (BUMEL) compared with carboplatin, etoposide, and melphalan (CEM)

Comparison groups	BUMEL (Cohort R1) v CEM (Cohort R1)

Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.049
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	8.084
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.011
upper limit	64.645

Statistical analysis title	Comparison of CI of sec. malignancies Cohort R2
Statistical analysis description:	
ch14.18/CHO (dinutuximab beta) and subcutaneous IL-2 compared with dinutuximab beta alone	
Comparison groups	STI ch14.18/CHO + scIL-2 (Cohort R2) v STI ch14.18/CHO (Cohort R2)
Number of subjects included in analysis	406
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.563
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.495
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.046
upper limit	5.366

Statistical analysis title	Comparison of CI of sec. malignancies Cohort R3
Statistical analysis description:	
difference in efficacy between MSKCC-N5 and rCOJEC: modified N7 vs Rapid COJEC	
Comparison groups	N7 (Cohort R3) v COJEC (Cohort R3)
Number of subjects included in analysis	626
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.255
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	0.385
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.074
upper limit	1.991

Statistical analysis title	Comparison of CI of sec. malignancies Cohort R4
Statistical analysis description:	
continuous infusion of ch14.18/CHO + retinoic acid (RA) ± aldesleukin (scIL-2): LTI ch14.18/CHO + RA + scIL-2 vs RA + LTI ch18.14/CHO	
Comparison groups	Retinoic acid (RA) + LTI ch14.18/CHO + scIL-2 (Cohort R4) v Retinoic acid (RA) + LTI ch14.18/CHO (Cohort R4)
Number of subjects included in analysis	405
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.682
Method	Wald test
Parameter estimate	Hazard ratio (HR)
Point estimate	1.366
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.307
upper limit	6.081

Other pre-specified: Number of febrile episodes per course	
End point title	Number of febrile episodes per course[26]
End point description:	
This endpoint is designated as the primary endpoint for cohort R0.	
End point type	Other pre-specified
End point timeframe:	
during COJEC	

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This study had a total of 5 randomizations. Endpoints were predefined on a cohort-specific basis in accordance with the scientific objectives of each cohort. As a result, not all endpoints are applicable to every study arm. "Number of febrile episodes per course" is not available for all treatment arms. This endpoint is designated as the primary endpoint for cohort R0.

End point values	PPGCSF (Cohort R0)	STGCSF (Cohort R0)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	119		
Units: Episodes/Cycle				
arithmetic mean (standard deviation)	2.3 (± 1.9)	3.1 (± 1.9)		

Statistical analyses

Statistical analysis title	Mean Difference Between Groups
Comparison groups	PPGCSF (Cohort R0) v STGCSF (Cohort R0)
Number of subjects included in analysis	238
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	0.763
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.284
upper limit	1.242

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Defined in the Study Protocol:
27 APPENDIX: Guidelines for Reporting Toxicity/Serious Adverse Events.

Adverse event reporting additional description:

The following events are exempt from reporting via the SAE CRF in the database:
• Relapse
• Signs and symptoms of disease progression
• Death from disease progression

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27

Reporting groups

Reporting group title	IND (randomised COJEC)
Reporting group description:	
Induction - randomised COJEC	
Reporting group title	IND (randomised N7)
Reporting group description:	
Induction - randomised N7	
Reporting group title	IND (not randomised)
Reporting group description:	
Induction - not randomised	
Reporting group title	TVD.
Reporting group description:	
TVD Topotecan, Vincristine, Doxorubicin	
Reporting group title	SURGERY
Reporting group description:	
Surgery	
Reporting group title	MAT (randomised BUMEL)
Reporting group description:	
Myeloablative therapy MAT - randomised BuMel - Busulfan (Busilvex), Melphalan	
Reporting group title	MAT (randomised CEM)
Reporting group description:	
Myeloablative therapy MAT - randomised CEM - Carboplatin, Etoposide, Melphalan	
Reporting group title	MAT (not randomised)
Reporting group description:	
Myeloablative therapy MAT - not randomised	
Reporting group title	RADIOTHERAPY
Reporting group description:	
Radiotherapy	
Reporting group title	MRD (R2 randomised GD2 only)
Reporting group description:	
Minimal residual disease MRD - R2 randomised GD2 only	
Reporting group title	MRD (R2 randomised GD2 + IL-2)
Reporting group description:	
Minimal residual disease MRD - R2 randomised GD2 + IL-2	
Reporting group title	MRD (R4 randomised GD2 only)

Reporting group description:

Minimal residual disease MRD - R4 randomised GD2 only

Reporting group title	MRD (R4 randomised GD2 + IL-2)

Reporting group description:

Minimal residual disease MRD - R4 randomised GD2 + IL-2

Reporting group title	MRD (not randomised)

Reporting group description:

Minimal residual disease MRD - not randomised

Reporting group title	Other occ. phase, missing

Reporting group description:

Other occurrence phase, missing

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Non-serious Adverse Events were not MedDRA coded but encountered toxicities were captured according to CTS coding in the clinical trial database.

Serious adverse events	IND (randomised COJEC)	IND (randomised N7)	IND (not randomised)
Total subjects affected by serious adverse events			
subjects affected / exposed	54 / 313 (17.25%)	103 / 316 (32.59%)	471 / 2830 (16.64%)
number of deaths (all causes)	2	1	8
number of deaths resulting from adverse events	2	1	8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary malignancy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Air embolism			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachiocephalic vein thrombosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Capillary leak syndrome			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Distributive shock			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	5 / 313 (1.60%)	2 / 316 (0.63%)	13 / 2830 (0.46%)
occurrences causally related to treatment / all	0 / 5	0 / 2	2 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	5 / 2830 (0.18%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic fistula			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphorrhoea			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract haemorrhage			

subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Adrenalectomy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder catheterisation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenostomy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodialysis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ventilation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrectomy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Resuscitation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombectomy			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Administration site extravasation			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Administration site swelling			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	1 / 313 (0.32%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extravasation			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal ulceration			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Oedema			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic graft versus host disease			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraftment syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serum sickness-like reaction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alpha haemolytic streptococcal infection			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 313 (0.32%)	1 / 316 (0.32%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial secretion retention			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chylothorax			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse alveolar damage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngospasm			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obliterative bronchiolitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary toxicity			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary veno-occlusive disease			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	5 / 2830 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal disorder			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed mood			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nightmare			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase			

increased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine increased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium increased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure systolic decreased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophil count increased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	1 / 313 (0.32%)	1 / 316 (0.32%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasoactive intestinal polypeptide increased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight increased			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic injury			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood stem cell transplant failure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory failure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic injury			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug dose omission by device			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraft failure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal procedural complication			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft complication			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Horner's syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incorrect dosage administered			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic duct injury			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal injury			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fistula			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural myocardial infarction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative adhesion			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative thrombosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural complication			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural hypotension			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural shock			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal procedural complication			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-related acute lung injury			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplantation complication			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava injury			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Cytogenetic abnormality			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroschisis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrioventricular block			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 313 (0.00%)	2 / 316 (0.63%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac failure acute			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac insuffiency			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Axonal neuropathy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Central nervous system lesion			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral atrophy			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgeusia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebellar infarction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemic seizure			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic intracranial hypertension			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			

subjects affected / exposed	1 / 313 (0.32%)	2 / 316 (0.63%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	12 / 2830 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 313 (0.00%)	2 / 316 (0.63%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematotoxicity			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoperitoneum			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 313 (0.32%)	3 / 316 (0.95%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 1	1 / 4	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet transfusion			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 313 (0.00%)	2 / 316 (0.63%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ototoxicity			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	11 / 2830 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Accommodation disorder			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anisocoria			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness transient			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cycloplegia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema of eyelid			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridoplegia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mydriasis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmoplegia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic discs blurred			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Opticus atrophy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital oedema			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Photophobia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pupil fixed			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cheilitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 313 (0.00%)	2 / 316 (0.63%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 313 (0.00%)	2 / 316 (0.63%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric pneumatosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal toxicity			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bowel			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralytic ileus			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis intestinalis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Severe diarrhoea			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	2 / 313 (0.64%)	2 / 316 (0.63%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	1 / 2	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis haemorrhagic			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus of small bowel			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 313 (0.32%)	6 / 316 (1.90%)	6 / 2830 (0.21%)
occurrences causally related to treatment / all	1 / 1	2 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jejunostomy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cytolysis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic displacement			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infarction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis cholestatic			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocholecystis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive disease			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			

subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis exfoliative			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin exfoliation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin toxicity			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	6 / 2830 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy toxic			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bladder			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	5 / 313 (1.60%)	2 / 316 (0.63%)	33 / 2830 (1.17%)
occurrences causally related to treatment / all	2 / 5	1 / 2	6 / 34
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Renal haemorrhage			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	5 / 2830 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular acidosis			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular disorder			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular dysfunction			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vein thrombosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal-limited thrombotic microangiopathy			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bacillus bacteraemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacillus infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida sepsis			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Citrobacter infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related bacteraemia			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 313 (0.32%)	1 / 316 (0.32%)	6 / 2830 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated aspergillosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection reactivation			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia pyelonephritis			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	9 / 313 (2.88%)	20 / 316 (6.33%)	30 / 2830 (1.06%)
occurrences causally related to treatment / all	6 / 17	16 / 42	15 / 44
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			

subjects affected / exposed	3 / 313 (0.96%)	1 / 316 (0.32%)	7 / 2830 (0.25%)
occurrences causally related to treatment / all	0 / 3	0 / 2	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fusarium infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis clostridial			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes virus infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningoencephalitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal gangrene			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	8 / 2830 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Influenza			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Moraxella infection			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis fungal			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parvovirus infection			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	5 / 2830 (0.18%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia adenoviral			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pneumonia aspiration			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cytomegaloviral			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	5 / 2830 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	3 / 2830 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	3 / 313 (0.96%)	7 / 316 (2.22%)	11 / 2830 (0.39%)
occurrences causally related to treatment / all	1 / 3	3 / 8	3 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection fungal			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Salmonellosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	3 / 313 (0.96%)	12 / 316 (3.80%)	30 / 2830 (1.06%)
occurrences causally related to treatment / all	1 / 4	3 / 12	9 / 40
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Septic shock			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	5 / 2830 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Serratia infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis aspergillus			

subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	9 / 2830 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	4 / 2830 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter sepsis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte depletion			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 313 (0.00%)	1 / 316 (0.32%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			

subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Refeeding syndrome			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	1 / 2830 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	1 / 313 (0.32%)	0 / 316 (0.00%)	2 / 2830 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	TVD.	SURGERY	MAT (randomised BUMEL)
Total subjects affected by serious adverse events			
subjects affected / exposed	66 / 1308 (5.05%)	104 / 2700 (3.85%)	58 / 296 (19.59%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Medulloblastoma			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary malignancy			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Air embolism			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachiocephalic vein thrombosis			

subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Capillary leak syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Distributive shock			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	1 / 1308 (0.08%)	6 / 2700 (0.22%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 1	0 / 6	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			

subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic fistula			
subjects affected / exposed	0 / 1308 (0.00%)	2 / 2700 (0.07%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphorrhoea			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Adrenalectomy			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder catheterisation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenostomy			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodialysis			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ventilation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrectomy			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Resuscitation			

subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombectomy			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Administration site extravasation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Administration site swelling			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	2 / 1308 (0.15%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extravasation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal ulceration			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 1308 (0.08%)	2 / 2700 (0.07%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic graft versus host disease			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraftment syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serum sickness-like reaction			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alpha haemolytic streptococcal infection			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial secretion retention			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chylothorax			

subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse alveolar damage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngospasm			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obliterative bronchiolitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 1308 (0.00%)	2 / 2700 (0.07%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary toxicity			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary veno-occlusive disease			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 1308 (0.00%)	2 / 2700 (0.07%)	2 / 296 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal disorder			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed mood			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nightmare			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine increased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium increased			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure systolic decreased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophil count increased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasoactive intestinal polypeptide increased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight increased			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic injury			
subjects affected / exposed	0 / 1308 (0.00%)	5 / 2700 (0.19%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood stem cell transplant failure			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory failure			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic injury			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug dose omission by device			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraft failure			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal procedural complication			

subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft complication			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Horner's syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incorrect dosage administered			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic duct injury			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal injury			

subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 1308 (0.00%)	2 / 2700 (0.07%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fistula			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural myocardial infarction			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative adhesion			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative thrombosis			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural complication			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			

subjects affected / exposed	0 / 1308 (0.00%)	3 / 2700 (0.11%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural hypotension			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural shock			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal procedural complication			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-related acute lung injury			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplantation complication			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava injury			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Cytogenetic abnormality			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroschisis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrioventricular block			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 1308 (0.00%)	2 / 2700 (0.07%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac failure			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac insuffiency			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Axonal neuropathy			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lesion			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral atrophy			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgeusia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebellar infarction			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemic seizure			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic intracranial hypertension			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	2 / 296 (0.68%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematotoxicity			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoperitoneum			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	2 / 1308 (0.15%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet transfusion			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	2 / 296 (0.68%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Hypoacusis			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ototoxicity			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Accommodation disorder			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anisocoria			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness transient			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cycloplegia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema of eyelid			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridoplegia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mydriasis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmoplegia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic discs blurred			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Opticus atrophy			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital oedema			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Photophobia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pupil fixed			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 1308 (0.08%)	7 / 2700 (0.26%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cheilitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric pneumatosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal toxicity			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 1308 (0.00%)	2 / 2700 (0.07%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	5 / 1308 (0.38%)	0 / 2700 (0.00%)	7 / 296 (2.36%)
occurrences causally related to treatment / all	1 / 5	0 / 0	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bowel			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralytic ileus			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis intestinalis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Severe diarrhoea			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	5 / 1308 (0.38%)	0 / 2700 (0.00%)	5 / 296 (1.69%)
occurrences causally related to treatment / all	4 / 7	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis haemorrhagic			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus of small bowel			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jejunostomy			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cytolysis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic displacement			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infarction			

subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis cholestatic			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocholecystis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive disease			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	8 / 296 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	7 / 296 (2.36%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis exfoliative			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin exfoliation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin toxicity			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy toxic			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bladder			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 1308 (0.08%)	6 / 2700 (0.22%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal haemorrhage			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular acidosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular disorder			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular dysfunction			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vein thrombosis			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal-limited thrombotic microangiopathy			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			

subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspergillus infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacillus bacteraemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacillus infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Citrobacter infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related bacteraemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated aspergillosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter infection			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection reactivation			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia pyelonephritis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	19 / 1308 (1.45%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	20 / 29	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			
subjects affected / exposed	0 / 1308 (0.00%)	2 / 2700 (0.07%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fusarium infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis clostridial			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	2 / 1308 (0.15%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes virus infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningoencephalitis			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal gangrene			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 1308 (0.08%)	2 / 2700 (0.07%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Moraxella infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis fungal			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parvovirus infection			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	1 / 1308 (0.08%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia adenoviral			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cytomegaloviral			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	4 / 1308 (0.31%)	2 / 2700 (0.07%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection fungal			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 1308 (0.15%)	5 / 2700 (0.19%)	4 / 296 (1.35%)
occurrences causally related to treatment / all	0 / 3	0 / 6	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia infection			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis aspergillus			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	1 / 1308 (0.08%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	2 / 1308 (0.15%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			

subjects affected / exposed	2 / 1308 (0.15%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter sepsis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	1 / 296 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 1308 (0.00%)	1 / 2700 (0.04%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte depletion			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			

subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Refeeding syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	MAT (randomised CEM)	MAT (not randomised)	RADIOTHERAPY
Total subjects affected by serious adverse events			
subjects affected / exposed	94 / 301 (31.23%)	310 / 1804 (17.18%)	42 / 2092 (2.01%)
number of deaths (all causes)	0	9	1
number of deaths resulting from adverse events	0	9	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary malignancy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Air embolism			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachiocephalic vein thrombosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Capillary leak syndrome			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Distributive shock			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	2 / 301 (0.66%)	3 / 1804 (0.17%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	2 / 301 (0.66%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic fistula			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphorrhoea			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Adrenalectomy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder catheterisation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenostomy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodialysis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ventilation			

subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrectomy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Resuscitation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombectomy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Administration site extravasation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Administration site swelling			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extravasation			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal ulceration			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	4 / 301 (1.33%)	3 / 1804 (0.17%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic graft versus host disease			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraftment syndrome			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serum sickness-like reaction			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter sepsis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alpha haemolytic streptococcal infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	2 / 301 (0.66%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 2	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial secretion retention			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chylothorax			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse alveolar damage			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngospasm			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 301 (0.00%)	3 / 1804 (0.17%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obliterative bronchiolitis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 301 (0.00%)	3 / 1804 (0.17%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			

subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	2 / 2092 (0.10%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 301 (0.00%)	6 / 1804 (0.33%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary toxicity			
subjects affected / exposed	1 / 301 (0.33%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary veno-occlusive disease			
subjects affected / exposed	0 / 301 (0.00%)	5 / 1804 (0.28%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 0
Respiratory distress			
subjects affected / exposed	1 / 301 (0.33%)	7 / 1804 (0.39%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	3 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 301 (0.33%)	8 / 1804 (0.44%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	4 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal disorder			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed mood			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nightmare			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure systolic decreased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Eosinophil count increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasoactive intestinal polypeptide increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight increased			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 301 (0.33%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aortic injury			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood stem cell transplant failure			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory failure			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic injury			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug dose omission by device			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraft failure			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal procedural complication			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft complication			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Horner's syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incorrect dosage administered			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic duct injury			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal injury			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fistula			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural myocardial infarction			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative adhesion			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative thrombosis			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural complication			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural hypotension			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural shock			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal procedural complication			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-related acute lung injury			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplantation complication			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava injury			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Cytogenetic abnormality			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroschisis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrioventricular block			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bradycardia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 301 (0.00%)	3 / 1804 (0.17%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac insuffiency			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Axonal neuropathy			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lesion			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral atrophy			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 301 (0.33%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgeusia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Haemorrhagic cerebellar infarction			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemic seizure			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic intracranial hypertension			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	2 / 301 (0.66%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematotoxicity			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoperitoneum			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet transfusion			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ototoxicity			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Accommodation disorder			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anisocoria			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness transient			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cycloplegia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema of eyelid			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridoplegia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mydriasis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmoplegia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic discs blurred			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Opticus atrophy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital oedema			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Photophobia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pupil fixed			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cheilitis			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 301 (0.33%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			

subjects affected / exposed	1 / 301 (0.33%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric pneumatosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			

subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal toxicity			
subjects affected / exposed	2 / 301 (0.66%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	1 / 301 (0.33%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	10 / 301 (3.32%)	14 / 1804 (0.78%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	1 / 10	0 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bowel			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralytic ileus			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis intestinalis			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Severe diarrhoea			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	2 / 301 (0.66%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	1 / 301 (0.33%)	8 / 1804 (0.44%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis haemorrhagic			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus of small bowel			

subjects affected / exposed	2 / 301 (0.66%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 301 (0.33%)	6 / 1804 (0.33%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jejunostomy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cytolysis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic displacement			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infarction			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis cholestatic			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	3 / 301 (1.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocholecystis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive disease			
subjects affected / exposed	3 / 301 (1.00%)	33 / 1804 (1.83%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	1 / 3	12 / 34	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			
subjects affected / exposed	0 / 301 (0.00%)	43 / 1804 (2.38%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	23 / 46	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis exfoliative			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin exfoliation			

subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin toxicity			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy toxic			
subjects affected / exposed	3 / 301 (1.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bladder			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	7 / 301 (2.33%)	5 / 1804 (0.28%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	3 / 7	1 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal haemorrhage			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular acidosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular disorder			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular dysfunction			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vein thrombosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal-limited thrombotic microangiopathy			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			

subjects affected / exposed	1 / 301 (0.33%)	3 / 1804 (0.17%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacillus bacteraemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacillus infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida sepsis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Citrobacter infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related bacteraemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated aspergillosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection reactivation			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia pyelonephritis			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	1 / 301 (0.33%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			
subjects affected / exposed	1 / 301 (0.33%)	6 / 1804 (0.33%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal sepsis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fusarium infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis clostridial			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes virus infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningoencephalitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal gangrene			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	2 / 301 (0.66%)	8 / 1804 (0.44%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Moraxella infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis fungal			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parvovirus infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	2 / 2092 (0.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	3 / 301 (1.00%)	2 / 1804 (0.11%)	2 / 2092 (0.10%)
occurrences causally related to treatment / all	1 / 3	2 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia adenoviral			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cytomegaloviral			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			

subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 301 (0.00%)	2 / 1804 (0.11%)	4 / 2092 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection fungal			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	6 / 301 (1.99%)	13 / 1804 (0.72%)	8 / 2092 (0.38%)
occurrences causally related to treatment / all	1 / 6	3 / 13	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Septic shock			
subjects affected / exposed	1 / 301 (0.33%)	6 / 1804 (0.33%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis aspergillus			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	2 / 2092 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas infection			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter sepsis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 301 (0.33%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte depletion			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			

subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 301 (0.00%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	1 / 301 (0.33%)	1 / 1804 (0.06%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	1 / 2092 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Refeeding syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	MRD (R2 randomised GD2 only)	MRD (R2 randomised GD2 + IL-2)	MRD (R4 randomised GD2 only)

Total subjects affected by serious adverse events			
subjects affected / exposed	82 / 200 (41.00%)	169 / 206 (82.04%)	57 / 205 (27.80%)
number of deaths (all causes)	2	0	0
number of deaths resulting from adverse events	2	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary malignancy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Air embolism			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachiocephalic vein thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Capillary leak syndrome			
subjects affected / exposed	0 / 200 (0.00%)	11 / 206 (5.34%)	4 / 205 (1.95%)
occurrences causally related to treatment / all	0 / 0	4 / 11	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Distributive shock			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	1 / 200 (0.50%)	3 / 206 (1.46%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic fistula			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphorrhoea			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Adrenalectomy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder catheterisation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenostomy			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodialysis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ventilation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrectomy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Resuscitation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombectomy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Administration site extravasation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Administration site swelling			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			

subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extravasation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal ulceration			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Oedema			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			

subjects affected / exposed	0 / 200 (0.00%)	2 / 206 (0.97%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 200 (0.50%)	2 / 206 (0.97%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 1	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	2 / 200 (1.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic graft versus host disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 200 (0.00%)	4 / 206 (1.94%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraftment syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 200 (0.00%)	8 / 206 (3.88%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	5 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serum sickness-like reaction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alpha haemolytic streptococcal infection			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial secretion retention			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	2 / 200 (1.00%)	2 / 206 (0.97%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	2 / 2	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chylothorax			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse alveolar damage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			

subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	2 / 200 (1.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngospasm			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obliterative bronchiolitis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary toxicity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary veno-occlusive disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			

subjects affected / exposed	4 / 200 (2.00%)	5 / 206 (2.43%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 4	2 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	2 / 205 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal disorder			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed mood			

subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nightmare			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood potassium increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure systolic decreased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophil count increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasoactive intestinal polypeptide increased			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight increased			

subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 200 (0.00%)	2 / 206 (0.97%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic injury			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood stem cell transplant failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic injury			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug dose omission by device			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraft failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal procedural complication			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft complication			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Horner's syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incorrect dosage administered			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic duct injury			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal injury			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fistula			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural myocardial infarction			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative adhesion			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural complication			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural hypotension			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural shock			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal procedural complication			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-related acute lung injury			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplantation complication			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava injury			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Cytogenetic abnormality			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroschisis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrioventricular block			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac insuffiency			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wolff-Parkinson-White syndrome			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Axonal neuropathy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lesion			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral atrophy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			

subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgeusia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 200 (0.00%)	2 / 206 (0.97%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	2 / 205 (0.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebellar infarction			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemic seizure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic intracranial hypertension			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 200 (0.00%)	2 / 206 (0.97%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 200 (0.00%)	4 / 206 (1.94%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			

subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematotoxicity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoperitoneum			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet transfusion			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	2 / 205 (0.98%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ototoxicity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Accommodation disorder			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anisocoria			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness transient			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cycloplegia			
subjects affected / exposed	0 / 200 (0.00%)	2 / 206 (0.97%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema of eyelid			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridoplegia			
subjects affected / exposed	1 / 200 (0.50%)	2 / 206 (0.97%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mydriasis			

subjects affected / exposed	1 / 200 (0.50%)	5 / 206 (2.43%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmoplegia			
subjects affected / exposed	0 / 200 (0.00%)	5 / 206 (2.43%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	2 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic discs blurred			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Opticus atrophy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital oedema			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Photophobia			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pupil fixed			
subjects affected / exposed	1 / 200 (0.50%)	3 / 206 (1.46%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			

subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 200 (0.00%)	3 / 206 (1.46%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cheilitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 200 (0.00%)	2 / 206 (0.97%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 200 (0.50%)	6 / 206 (2.91%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric pneumatosis			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal toxicity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			

subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	3 / 205 (1.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bowel			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralytic ileus			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis intestinalis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Severe diarrhoea			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis haemorrhagic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus of small bowel			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 200 (1.00%)	6 / 206 (2.91%)	3 / 205 (1.46%)
occurrences causally related to treatment / all	0 / 2	1 / 7	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jejunostomy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cytolysis			

subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic displacement			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infarction			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis cholestatic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocholecystis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis exfoliative			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			

subjects affected / exposed	2 / 200 (1.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin exfoliation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin toxicity			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy toxic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bladder			

subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 200 (0.50%)	6 / 206 (2.91%)	2 / 205 (0.98%)
occurrences causally related to treatment / all	1 / 1	1 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal haemorrhage			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular acidosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular disorder			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular dysfunction			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vein thrombosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal-limited thrombotic microangiopathy			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacillus bacteraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacillus infection			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Citrobacter infection			

subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related bacteraemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated aspergillosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter infection			
subjects affected / exposed	2 / 200 (1.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection reactivation			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			

subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia pyelonephritis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fusarium infection			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis clostridial			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	3 / 200 (1.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes virus infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningoencephalitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal gangrene			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Moraxella infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis fungal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parvovirus infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia adenoviral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cytomegaloviral			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	4 / 200 (2.00%)	14 / 206 (6.80%)	4 / 205 (1.95%)
occurrences causally related to treatment / all	0 / 5	1 / 19	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection fungal			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	4 / 200 (2.00%)	7 / 206 (3.40%)	3 / 205 (1.46%)
occurrences causally related to treatment / all	0 / 5	4 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia infection			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis aspergillus			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			

subjects affected / exposed	2 / 200 (1.00%)	2 / 206 (0.97%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 200 (0.50%)	0 / 206 (0.00%)	1 / 205 (0.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	2 / 205 (0.98%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter sepsis			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte depletion			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	1 / 200 (0.50%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 200 (0.00%)	1 / 206 (0.49%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Refeeding syndrome			

subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	MRD (R4 randomised GD2 + IL-2)	MRD (not randomised)	Other occ. phase, missing
Total subjects affected by serious adverse events			
subjects affected / exposed	68 / 202 (33.66%)	104 / 975 (10.67%)	145 / 3566 (4.07%)
number of deaths (all causes)	4	1	6
number of deaths resulting from adverse events	4	1	6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	5 / 3566 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	3 / 3566 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary malignancy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Air embolism			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachiocephalic vein thrombosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Capillary leak syndrome			

subjects affected / exposed	6 / 202 (2.97%)	3 / 975 (0.31%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	6 / 7	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Distributive shock			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	2 / 975 (0.21%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemorrhage intracranial			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic fistula			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphorrhoea			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract haemorrhage			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Adrenalectomy			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder catheterisation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenostomy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodialysis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ventilation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrectomy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Resuscitation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombectomy			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Administration site extravasation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Administration site swelling			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extravasation			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal ulceration			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	8 / 3566 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 202 (0.00%)	2 / 975 (0.21%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic graft versus host disease			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraftment syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	1 / 202 (0.50%)	2 / 975 (0.21%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serum sickness-like reaction			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter sepsis			
subjects affected / exposed	1 / 202 (0.50%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alpha haemolytic streptococcal infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	4 / 3566 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial secretion retention			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chylothorax			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse alveolar damage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngospasm			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obliterative bronchiolitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 202 (0.50%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary toxicity			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary veno-occlusive disease			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	2 / 202 (0.99%)	0 / 975 (0.00%)	4 / 3566 (0.11%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal disorder			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed mood			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nightmare			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase			

increased			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine increased			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium increased			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure systolic decreased			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophil count increased			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasoactive intestinal polypeptide increased			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight increased			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic injury			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood stem cell transplant failure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain herniation			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory failure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic injury			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug dose omission by device			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Engraft failure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	2 / 202 (0.99%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal procedural complication			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft complication			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Horner's syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incorrect dosage administered			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic duct injury			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal injury			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			

subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fistula			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural myocardial infarction			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative adhesion			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative thrombosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural complication			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural hypotension			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural shock			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal procedural complication			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-related acute lung injury			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplantation complication			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava injury			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong product administered			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Cytogenetic abnormality			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroschisis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrioventricular block			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac failure acute			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac insuffiency			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	1 / 202 (0.50%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Axonal neuropathy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lesion			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral atrophy			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysgeusia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebellar infarction			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemic seizure			

subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic intracranial hypertension			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	2 / 202 (0.99%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematotoxicity			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Haemoperitoneum			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet transfusion			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ototoxicity			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Accommodation disorder			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anisocoria			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness transient			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cycloplegia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema of eyelid			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridoplegia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mydriasis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmoplegia			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic discs blurred			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Opticus atrophy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital oedema			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Photophobia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pupil fixed			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 202 (0.50%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cheilitis			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 202 (0.50%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 202 (0.50%)	2 / 975 (0.21%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric pneumatosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 202 (0.50%)	2 / 975 (0.21%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal toxicity			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 202 (0.00%)	2 / 975 (0.21%)	3 / 3566 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bowel			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralytic ileus			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis intestinalis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Severe diarrhoea			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis haemorrhagic			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus of small bowel			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Jejunostomy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cytolysis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic displacement			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic infarction			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis cholestatic			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocholecystis			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive disease			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venoocclusive liver disease			

subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	3 / 3566 (0.08%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis exfoliative			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin exfoliation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin toxicity			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			

subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy toxic			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bladder			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	3 / 202 (1.49%)	1 / 975 (0.10%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	3 / 3	1 / 1	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Renal haemorrhage			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular acidosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular disorder			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular dysfunction			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal vein thrombosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal-limited thrombotic microangiopathy			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acinetobacter infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillus infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bacillus bacteraemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacillus infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida sepsis			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Citrobacter infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related bacteraemia			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated aspergillosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal sepsis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr virus infection reactivation			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia pyelonephritis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 202 (0.00%)	3 / 975 (0.31%)	3 / 3566 (0.08%)
occurrences causally related to treatment / all	0 / 0	1 / 3	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			

subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	3 / 3566 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal sepsis			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fusarium infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis clostridial			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes virus infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningoencephalitis			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal gangrene			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 202 (0.00%)	2 / 975 (0.21%)	8 / 3566 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Moraxella infection			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis fungal			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parvovirus infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 202 (0.50%)	1 / 975 (0.10%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia adenoviral			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cytomegaloviral			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	7 / 202 (3.47%)	7 / 975 (0.72%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	7 / 10	2 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection fungal			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 202 (0.99%)	10 / 975 (1.03%)	4 / 3566 (0.11%)
occurrences causally related to treatment / all	1 / 2	0 / 10	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Septic shock			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	4 / 3566 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serratia infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis aspergillus			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	2 / 3566 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter sepsis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte depletion			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			

subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	3 / 202 (1.49%)	8 / 975 (0.82%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	2 / 3	3 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 202 (0.00%)	1 / 975 (0.10%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	1 / 202 (0.50%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	1 / 3566 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			

subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Refeeding syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	IND (randomised COJEC)	IND (randomised N7)	IND (not randomised)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 313 (0.00%)	0 / 316 (0.00%)	0 / 2830 (0.00%)

Non-serious adverse events	TVD.	SURGERY	MAT (randomised BUMEL)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1308 (0.00%)	0 / 2700 (0.00%)	0 / 296 (0.00%)

Non-serious adverse events	MAT (randomised CEM)	MAT (not randomised)	RADIOTHERAPY
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 301 (0.00%)	0 / 1804 (0.00%)	0 / 2092 (0.00%)

Non-serious adverse events	MRD (R2 randomised GD2	MRD (R2 randomised GD2 +	MRD (R4 randomised GD2

	only)	IL-2)	only)
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 200 (0.00%)	0 / 206 (0.00%)	0 / 205 (0.00%)

Non-serious adverse events	MRD (R4 randomised GD2 + IL-2)	MRD (not randomised)	Other occ. phase, missing
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 202 (0.00%)	0 / 975 (0.00%)	0 / 3566 (0.00%)

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 November 2005	Amendment 1
10 March 2006	Amendment 2
31 July 2007	Amendment 3
01 July 2009	Amendment 4
01 June 2011	Amendment 5, HR-NBL1.5 SIOPEN
01 August 2013	Amendment 6, HR-NBL1.6 SIOPEN
04 April 2014	Amendment 7, HR-NBL1.7 SIOPEN
15 September 2017	Amendment 8, HR-NBL1.8 SIOPEN
12 December 2022	Amendment 9, HR-NBL1.9 SIOPEN

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28259608

http://www.ncbi.nlm.nih.gov/pubmed/30442501

http://www.ncbi.nlm.nih.gov/pubmed/32013055

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