Clinical trial results:
A Phase 1/2 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of MEDI4736 in Subjects With Advanced Solid Tumors

Summary

EudraCT number	2012-002206-52
Trial protocol	BE GB DK
Global end of trial date	28 February 2020

Results information

Result version number	v2 (current)
This version publication date	07 May 2021
First version publication date	13 March 2021
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	CD-ON-MEDI4736-1108

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01693562
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedImmune, LLC
Sponsor organisation address	One MedImmune Way, Gaithersburg, United States, 20878
Public contact	Ashok Gupta, MedImmune, LLC, +1 3013981287, information.center@astrazeneca.com
Scientific contact	Ashok Gupta, MedImmune, LLC, +1 3013981287, information.center@astrazeneca.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 April 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 February 2020
Global end of trial reached?	Yes
Global end of trial date	28 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objectives of the study are: 1. To determine maximum tolerated dose or optimal biologic dose of MEDI4736 in dose-escalation phase 2. Safety profile of MEDI4736 in dose-escalation, dose-exploration, dose-expansion phases 3. Antitumor activity of MEDI4736 in dose-expansion phase in participants with programmed death ligand 1 (PD-L1) positive urothelial bladder cancer (UBC) who had received 1 line of prior therapy (2L+), in participants with non-squamous non-small cell lung cancer (NSCLC) who had received 2 or more lines of prior therapy (3L+), and in participants with squamous NSCLC who had received 1 line of prior therapy (2L+) and 2 or more lines of prior therapy (3L+). Antitumor activity was assessed by Blinded Independent Central Review (BICR) based on Response Evaluation Criteria in Solid Tumors (RECIST) version (v) 1.1.

Protection of trial subjects:

The conduct of this clinical study met all local and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with International Conference on Harmonization guideline: Good Clinical Practice, and applicable regulatory requirements. Participants signed an informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 August 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 29
Country: Number of subjects enrolled	Canada: 55
Country: Number of subjects enrolled	Germany: 29
Country: Number of subjects enrolled	France: 66
Country: Number of subjects enrolled	United Kingdom: 41
Country: Number of subjects enrolled	Italy: 47
Country: Number of subjects enrolled	Korea, Republic of: 73
Country: Number of subjects enrolled	Taiwan: 3
Country: Number of subjects enrolled	United States: 681

Worldwide total number of subjects	1024
EEA total number of subjects	171

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	570
From 65 to 84 years	448
85 years and over	6

Subject disposition

Recruitment

Recruitment details:

The study was conducted in Belgium, Canada, France, Germany, Italy, South Korea, Taiwan, UK, and USA.

Pre-assignment

Screening details:

N=1022 participants were enrolled, not N=1024 indicated in participant flow. Discrepancy is due to duplicate reporting of n=2 NSCLC participants. Once in 10mg/kg dose-escalation cohort (total N=6) and again in with N=302 NSCLC participants from 10mg/kg dose expansion cohort (total N=304).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)

Arm description:

Participants received intravenous (IV) infusion of MEDI4736 (durvalumab) 0.1 mg/kg every 2 weeks (Q2W) in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 0.1 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)

Arm description:

Participants received IV infusion of MEDI4736 0.3 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 0.3 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Escalation Cohort (MEDI4736 1 mg/kg Q2W)

Arm description:

Participants received IV infusion of MEDI4736 1 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 1 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Escalation Cohort (MEDI4736 3 mg/kg Q2W)

Arm description:

Participants received IV infusion of MEDI4736 3 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 3 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Escalation Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Escalation Cohort (MEDI4736 15 mg/kg Q3W)

Arm description:

Participants received IV infusion of MEDI4736 15 mg/kg every 3 weeks (Q3W) in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 15 mg/kg was administered as IV infusion Q3W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Exploration Cohort (MEDI4736 20 mg/kg Q4W)

Arm description:

Participants received IV infusion of MEDI4736 20 mg/kg every 4 weeks (Q4W) in the dose-exploration phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 20 mg/kg was administered as IV infusion Q4W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with squamous cell carcinoma of the head and neck (SCCHN) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with non-SCCHN human papilloma virus positive (Non-SCCHN HPV+) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until

confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with non-small-cell lung cancer (NSCLC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with hepatocellular carcinoma (HCC Total) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with advance cutaneous melanoma (ACM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with uveal melanoma (UM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with gastroesophageal cancer (GEC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with triple-negative breast cancer (TNBC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with pancreatic adenocarcinoma (PAC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with urothelial carcinoma (UC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with glioblastoma multiforme (GBM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose- expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with ovarian cancer (OC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until

confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with soft- tissue sarcoma (STS) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with small-cell lung cancer (SCLC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with microsatellite instability (MSI)-high cancer received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm title	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)

Arm description:

Participants with nasopharyngeal carcinoma (NPC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose- expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab 10 mg/kg was administered as IV infusion Q2W for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Number of subjects in period 1	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 1 mg/kg Q2W)
Started	4	4	3
Completed	0	0	0
Not completed	4	4	3
Adverse event, serious fatal	1	1	-
Consent withdrawn by subject	-	1	-
Death	3	1	-
Unspecified	-	-	2
Lost to follow-up	-	1	1

Number of subjects in period 1	Escalation Cohort (MEDI4736 3 mg/kg Q2W)	Escalation Cohort (MEDI4736 10 mg/kg Q2W)	Escalation Cohort (MEDI4736 15 mg/kg Q3W)
Started	3	6	7
Completed	0	0	0
Not completed	3	6	7
Adverse event, serious fatal	1	1	1
Consent withdrawn by subject	-	-	2
Death	2	5	3
Unspecified	-	-	1
Lost to follow-up	-	-	-

Number of subjects in period 1	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)
Started	21	62	22
Completed	0	0	0
Not completed	21	62	22
Adverse event, serious fatal	8	14	8

Consent withdrawn by subject	2	16	2
Death	9	28	9
Unspecified	2	3	1
Lost to follow-up	-	1	2

Number of subjects in period 1	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)
Started	304	40	21
Completed	4	0	0
Not completed	300	40	21
Adverse event, serious fatal	88	10	5
Consent withdrawn by subject	54	2	2
Death	120	20	3
Unspecified	28	4	7
Lost to follow-up	10	4	4

Number of subjects in period 1	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)
Started	24	51	40
Completed	1	0	0
Not completed	23	51	40
Adverse event, serious fatal	7	19	8
Consent withdrawn by subject	3	5	16
Death	12	23	15
Unspecified	-	1	1
Lost to follow-up	1	3	-

Number of subjects in period 1	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)
Started	31	201	20
Completed	0	4	0
Not completed	31	197	20
Adverse event, serious fatal	13	71	2
Consent withdrawn by subject	7	40	4
Death	10	57	14
Unspecified	-	28	-
Lost to follow-up	1	1	-

Number of subjects in period 1	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)
Started	47	20	21
Completed	0	0	0
Not completed	47	20	21
Adverse event, serious fatal	8	1	9

Consent withdrawn by subject	8	3	1
Death	28	15	8
Unspecified	1	-	1
Lost to follow-up	2	1	2

Number of subjects in period 1	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)
Started	62	10
Completed	0	0
Not completed	62	10
Adverse event, serious fatal	14	4
Consent withdrawn by subject	8	1
Death	21	3
Unspecified	17	1
Lost to follow-up	2	1

Reporting groups

Reporting group title	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)

Reporting group description:

Participants received intravenous (IV) infusion of MEDI4736 (durvalumab) 0.1 mg/kg every 2 weeks (Q2W) in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 0.3 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 1 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 1 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 3 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 3 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 15 mg/kg Q3W)

Reporting group description:

Participants received IV infusion of MEDI4736 15 mg/kg every 3 weeks (Q3W) in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Exploration Cohort (MEDI4736 20 mg/kg Q4W)

Reporting group description:

Participants received IV infusion of MEDI4736 20 mg/kg every 4 weeks (Q4W) in the dose-exploration phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with squamous cell carcinoma of the head and neck (SCCHN) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with non-SCCHN human papilloma virus positive (Non-SCCHN HPV+) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with non-small-cell lung cancer (NSCLC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with hepatocellular carcinoma (HCC Total) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with advance cutaneous melanoma (ACM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with uveal melanoma (UM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with gastroesophageal cancer (GEC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with triple-negative breast cancer (TNBC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with pancreatic adenocarcinoma (PAC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with urothelial carcinoma (UC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with glioblastoma multiforme (GBM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose- expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with ovarian cancer (OC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with soft- tissue sarcoma (STS) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with small-cell lung cancer (SCLC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with microsatellite instability (MSI)-high cancer received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with nasopharyngeal carcinoma (NPC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose- expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group values	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 1 mg/kg Q2W)
Number of subjects	4	4	3
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	0	1
From 65-84 years	2	4	2
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	58.5	68.0	65.3
standard deviation	± 9.0	± 2.9	± 19.3
Sex: Female, Male Units: Participants			
Female	2	1	2
Male	2	3	1
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaskan Native	0	0	0
Asian	0	0	0
Black or African American	0	1	0

Native Hawaiian or Other Pacific Islander	0	0	0
White	4	3	2
Other	0	0	0
Multiple	0	0	0
Missing	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	3	4	2
Unknown or Not Reported	0	0	1

Reporting group values	Escalation Cohort (MEDI4736 3 mg/kg Q2W)	Escalation Cohort (MEDI4736 10 mg/kg Q2W)	Escalation Cohort (MEDI4736 15 mg/kg Q3W)
Number of subjects	3	6	7
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	6	4
From 65-84 years	1	0	3
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	57.0	48.8	55.9
standard deviation	± 13.7	± 9.7	± 16.9
Sex: Female, Male Units: Participants			
Female	2	2	2
Male	1	4	5
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaskan Native	0	0	0
Asian	1	0	0
Black or African American	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	2	6	7
Other	0	0	0
Multiple	0	0	0
Missing	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	1
Not Hispanic or Latino	3	5	6
Unknown or Not Reported	0	0	0

Reporting group values	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)
Number of subjects	21	62	22
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	12	41	19
From 65-84 years	9	20	3
85 years and over	0	1	0
Age Continuous Units: years			
arithmetic mean	64.9	58.2	53.5
standard deviation	± 9.6	± 12.0	± 10.2
Sex: Female, Male Units: Participants			
Female	5	9	15
Male	16	53	7
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaskan Native	0	0	0
Asian	0	5	1
Black or African American	1	1	2
Native Hawaiian or Other Pacific Islander	0	1	0
White	19	49	19
Other	1	2	0
Multiple	0	0	0
Missing	0	4	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	5	1
Not Hispanic or Latino	19	54	21
Unknown or Not Reported	0	3	0

Reporting group values	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)
Number of subjects	304	40	21
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0

Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	146	26	12
From 65-84 years	156	14	9
85 years and over	2	0	0
Age Continuous			
Units: years			
arithmetic mean	63.8	58.1	58.9
standard deviation	± 11.0	± 14.0	± 14.3
Sex: Female, Male			
Units: Participants			
Female	133	8	9
Male	171	32	12
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaskan Native	0	0	0
Asian	58	9	0
Black or African American	10	3	1
Native Hawaiian or Other Pacific Islander	0	2	0
White	227	19	19
Other	4	1	0
Multiple	0	0	0
Missing	5	6	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	12	2	2
Not Hispanic or Latino	287	32	19
Unknown or Not Reported	5	6	0

Reporting group values	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)
Number of subjects	24	51	40
Age categorical			
Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	14	33	35
From 65-84 years	10	18	5
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	61.3	58.1	51.2
standard deviation	± 10.2	± 11.5	± 10.6

Sex: Female, Male Units: Participants			
Female	10	13	40
Male	14	38	0
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaskan Native	0	0	0
Asian	0	1	2
Black or African American	0	1	6
Native Hawaiian or Other Pacific Islander	0	0	0
White	19	45	25
Other	0	0	1
Multiple	0	1	0
Missing	5	3	6
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	4	0
Not Hispanic or Latino	18	43	33
Unknown or Not Reported	5	4	7

Reporting group values	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)
Number of subjects	31	201	20
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	16	77	16
From 65-84 years	15	122	4
85 years and over	0	2	0
Age Continuous Units: years			
arithmetic mean	62.6	66.1	56.0
standard deviation	± 10.2	± 9.4	± 13.0
Sex: Female, Male Units: Participants			
Female	9	58	7
Male	22	143	13
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaskan Native	0	0	0
Asian	0	40	0
Black or African American	1	8	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	29	128	19

Other	1	5	1
Multiple	0	1	0
Missing	0	19	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	5	2
Not Hispanic or Latino	30	177	18
Unknown or Not Reported	0	19	0

Reporting group values	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)
Number of subjects	47	20	21
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	30	15	9
From 65-84 years	16	5	12
85 years and over	1	0	0
Age Continuous Units: years			
arithmetic mean	59.7	53.2	64.8
standard deviation	± 12.5	± 15.7	± 11.6
Sex: Female, Male Units: Participants			
Female	47	15	8
Male	0	5	13
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaskan Native	0	0	0
Asian	4	1	2
Black or African American	1	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	36	18	17
Other	0	0	1
Multiple	0	0	0
Missing	6	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	5	1
Not Hispanic or Latino	39	15	20
Unknown or Not Reported	6	0	0

Reporting group values	Expansion MSI-high Cancer Cohort (MEDI4736 10	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)	Total

	mg/kg Q2W)		
Number of subjects	62	10	1024
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	47	7	570
From 65-84 years	15	3	448
85 years and over	0	0	6
Age Continuous Units: years			
arithmetic mean	54.3	54.0	
standard deviation	± 13.4	± 19.0	-
Sex: Female, Male Units: Participants			
Female	34	3	434
Male	28	7	590
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaskan Native	0	0	0
Asian	6	5	135
Black or African American	2	0	40
Native Hawaiian or Other Pacific Islander	0	2	5
White	34	3	749
Other	4	0	21
Multiple	0	0	2
Missing	16	0	72
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	4	0	52
Not Hispanic or Latino	42	10	900
Unknown or Not Reported	16	0	72

End points reporting groups

Reporting group title	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)

Reporting group description:

Participants received intravenous (IV) infusion of MEDI4736 (durvalumab) 0.1 mg/kg every 2 weeks (Q2W) in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 0.3 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 1 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 1 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 3 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 3 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 15 mg/kg Q3W)

Reporting group description:

Participants received IV infusion of MEDI4736 15 mg/kg every 3 weeks (Q3W) in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Exploration Cohort (MEDI4736 20 mg/kg Q4W)

Reporting group description:

Participants received IV infusion of MEDI4736 20 mg/kg every 4 weeks (Q4W) in the dose-exploration phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with squamous cell carcinoma of the head and neck (SCCHN) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with non-SCCHN human papilloma virus positive (Non-SCCHN HPV+) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with non-small-cell lung cancer (NSCLC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with hepatocellular carcinoma (HCC Total) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with advance cutaneous melanoma (ACM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with uveal melanoma (UM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with gastroesophageal cancer (GEC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with triple-negative breast cancer (TNBC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with pancreatic adenocarcinoma (PAC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with urothelial carcinoma (UC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with glioblastoma multiforme (GBM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose- expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with ovarian cancer (OC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with soft- tissue sarcoma (STS) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with small-cell lung cancer (SCLC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with microsatellite instability (MSI)-high cancer received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with nasopharyngeal carcinoma (NPC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose- expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Subject analysis set title	Escalation/Expansion Cohort (Total MEDI4736 10 mg/kg Q2W)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-escalation or dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Subject analysis set title	Expansion Non-squamous NSCLC 3L+ Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with non-squamous NSCLC who had received 2 or more lines of prior therapy (3L+) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Subject analysis set title	Expansion Squamous NSCLC 3L+ Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with squamous NSCLC who had received 2 or more lines of prior therapy (3L+) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Subject analysis set title	Expansion Squamous NSCLC 2L+ Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with squamous NSCLC who had received at least 1 line of prior therapy (2L+) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Subject analysis set title	Expansion UC PD-L1 high 2L+ Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with UC (post-platinum PD-L1 status high) who had received at least 1 line of prior therapy (2L+) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Subject analysis set title	Total Escalation/Exploration Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received IV infusion of MEDI4736 0.1 mg/kg, 0.3 mg/kg, 1 mg/kg, 3 mg/kg, and 10 mg/kg Q2W, and 15 mg/kg Q3W in the dose-escalation phase; and 20 mg/kg Q4W in the dose-exploration phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Subject analysis set title	Expansion UC PD-L1 low/Negative Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with UC (PD-L1 status low/negative) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Subject analysis set title	Expansion UC Total Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with UC (Total PD-L1 status - high, low/negative, and unknown) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Subject analysis set title	Expansion UC PD-L1 high Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with UC (PD-L1 status high) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Primary: Number of Participants With Dose-limiting Toxicities in the Dose-escalation Phase

End point title	Number of Participants With Dose-limiting Toxicities in the Dose-escalation Phase[1][2]

End point description:

A DLT was defined as any Grade 3 or higher treatment-related toxicity that occurred during the DLT-evaluation period including any >= Grade 3 colitis or >= Grade 3 immune-related adverse event (irAE; AEs of immune nature in the absence of a clear alternative etiology) including rash, pruritus, or diarrhea that did not downgrade to =< Grade 2 within 3 days after onset of the event despite maximal supportive care including systemic corticosteroids. The DLT-evaluation period for 0.1 to 10 mg/kg arms was from Day 1 to Day 28 of first dose and for 15 mg/kg arm was from Day 1 to Day 42 of first dose. Participants in DLT-evaluable population (participants in the dose-escalation phase who received at least 2 doses of study drug and completed safety follow-up through DLT-evaluable period or experienced any DLT during the DLT-evaluation period) were analysed.

End point type	Primary

End point timeframe:

For MEDI4736 0.1 to MEDI4736 10 mg/kg arms: from Day 1 to Day 28 of first dose; for MEDI4736 15 mg/kg arm: from Day 1 to Day 42 of first dose

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[2] - 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 1 mg/kg Q2W)	Escalation Cohort (MEDI4736 3 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: Participants	0	0	0	0

End point values	Escalation Cohort (MEDI4736 10 mg/kg Q2W)	Escalation Cohort (MEDI4736 15 mg/kg Q3W)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-emergent Adverse Events (TEAEs) and Treatment-emergent Serious Adverse Events (TESAEs) in the Dose-escalation, Dose-exploration, and Dose-expansion Phase

End point title	Number of Participants With Treatment-emergent Adverse Events (TEAEs) and Treatment-emergent Serious Adverse Events (TESAEs) in the Dose-escalation, Dose-exploration, and Dose-expansion Phase[3][4]

End point description:

An adverse event (AE) is any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. A serious adverse event (SAE) is an AE resulting in any of these outcomes: death; initial or prolonged inpatient hospitalization; life threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. The TEAEs are defined as events present at baseline that worsened in intensity after administration of study drug or events absent at baseline that emerged after administration of study drug. As-treated population included all participants who received any dose of study drug. Participants enrolled in the 10 mg/kg Q2W Expansion and Escalation Cohort have been summarised as a total only because the safety profile of durvalumab monotherapy 10 mg/kg Q2W was manageable and generally consistent with the known safety profile of the anti-programmed cell death ligand (PD-L1/PD-1) drug class.

End point type	Primary

End point timeframe:

From Day 1 through 90 days after the last dose of study drug (approximately 5.25 years)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 1 mg/kg Q2W)	Escalation Cohort (MEDI4736 3 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: Participants				
Any TEAEs	3	4	3	3
Any TESAEs	1	2	1	1

End point values	Escalation Cohort (MEDI4736 15 mg/kg Q3W)	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	Escalation/Expansion Cohort (Total MEDI4736 10 mg/kg Q2W)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	21	980	
Units: Participants				
Any TEAEs	7	21	963	
Any TESAEs	3	13	536	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Abnormal Clinical Laboratory Parameters Reported as TEAEs in the Dose-escalation, Dose-exploration, and Dose-expansion phase

End point title	Number of Participants With Abnormal Clinical Laboratory Parameters Reported as TEAEs in the Dose-escalation, Dose-exploration, and Dose-expansion phase[5][6]

End point description:

Number of participants with abnormal clinical laboratory parameters reported as TEAEs are reported. Abnormal clinical laboratory parameters defined as any abnormal finding during analysis of coagulation, urine, hematology, and serum chemistry. As-treated population included all participants who received any dose of study drug. Participants enrolled in the 10 mg/kg Q2W Expansion and Escalation Cohort have been summarised as a total only. This is because the safety profile of durvalumab monotherapy 10 mg/kg Q2W was manageable and generally consistent with the known safety profile of the anti-PD-L1/PD-1 drug class.

End point type	Primary

End point timeframe:

From Day 1 through 90 days after the last dose of study drug (approximately 5.25 years)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 1 mg/kg Q2W)	Escalation Cohort (MEDI4736 3 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: Participants				
Anaemia	1	0	0	0
Thrombocytopenia	0	0	0	0
White blood cell count increased	0	0	0	0
Leukocytosis	0	0	0	0
Lymphocyte count decreased	0	0	0	0
Neutropenia	0	0	0	0
Leukopenia	0	0	0	0
Thrombocytosis	0	0	0	0
Iron deficiency anaemia	0	0	0	0
Haemoglobin decreased	0	0	0	0
Neutrophil count increased	0	0	0	0
Red blood cell count decreased	0	0	0	0
Anaemia of chronic disease	0	0	0	0
Eosinophilia	0	0	0	0
Haemolysis	0	0	0	0
Leukostasis syndrome	0	0	0	0
Immune thrombocytopenic purpura	0	0	0	0
International normalised ratio increased	0	0	0	0
Activated partial thromboplastin time prolonged	0	0	0	0
Blood fibrinogen increased	0	0	0	0
Platelet count decreased	0	0	0	0
Disseminated intravascular coagulation	0	0	0	0
Prothrombin time prolonged	0	0	0	0
Activated partial thromboplastin time shortened	0	0	0	0
Coagulation factor increased	0	0	0	0
Coagulopathy	0	0	0	0
Alanine aminotransferase increased	0	0	1	0
Aspartate aminotransferase increased	0	0	1	0
Blood alkaline phosphatase increased	0	0	1	0
Blood bilirubin increased	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	0
Hyperbilirubinaemia	0	0	0	0
Transaminases increased	0	0	0	0
Blood lactate dehydrogenase increased	0	0	0	0
Hepatic function abnormal	0	0	0	0
Alanine aminotransferase decreased	0	0	0	0
Aspartate aminotransferase decreased	0	0	0	0
Blood albumin decreased	0	0	0	0
Hepatic enzyme increased	0	0	0	0
Liver function test increased	0	0	0	0
White blood cell count decreased	0	0	0	0
Neutrophil count decreased	0	0	0	0
Lymphopenia	0	0	0	0
Blood creatinine increased	0	1	1	0

Hyperuricaemia	0	0	0	0
Blood urea increased	0	0	0	0
Glomerular filtration rate decreased	0	0	0	0
Hypothyroidism	0	1	1	0
Hyperthyroidism	0	0	0	0
Blood thyroid stimulating hormone increased	0	0	0	0
Blood thyroid stimulating hormone decreased	0	0	0	0
Thyroxine decreased	0	0	0	0
Thyroxine free decreased	0	0	0	0
Thyroxine free increased	0	0	0	0
Tri-iodothyronine free decreased	0	0	0	0
Thyroxine increased	0	0	0	0
Tri-iodothyronine decreased	0	0	0	0
Tri-iodothyronine increased	0	0	0	0
Hyponatraemia	0	0	1	0
Hypomagnesaemia	0	0	0	0
Hypercalcaemia	0	0	0	0
Hyperglycaemia	0	0	1	0
Hypokalaemia	0	0	0	0
Hypocalcaemia	0	0	0	0
Hypophosphataemia	0	0	0	0
Hypertriglyceridaemia	0	0	0	0
Hypoglycaemia	0	0	0	0
Blood cholesterol increased	0	0	0	0
Blood magnesium decreased	0	0	0	0
Blood triglycerides increased	0	0	0	0
Blood glucose increased	0	0	0	0
Hypercholesterolaemia	0	0	0	0
Blood potassium increased	0	0	0	0
Blood chloride increased	0	0	0	0
Blood electrolytes decreased	0	0	0	0
Blood potassium decreased	0	0	0	0
Hyperphosphataemia	0	0	0	0
Protein total decreased	0	0	0	0
Protein urine present	0	0	0	0
Blood bicarbonate decreased	0	0	0	0
Blood chloride decreased	0	0	0	0
Blood sodium decreased	0	0	0	0
Hypermagnesaemia	0	0	0	0
Hypernatraemia	0	0	0	0
Hypochloraemia	0	0	0	0
Hypoproteinaemia	0	0	0	0
Hyperkalaemia	0	0	0	0

End point values	Escalation Cohort (MEDI4736 15 mg/kg Q3W)	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	Escalation/Expansion Cohort (Total MEDI4736 10 mg/kg Q2W)	

Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	21	980	
Units: Participants				
Anaemia	0	0	166	
Thrombocytopenia	0	1	24	
White blood cell count increased	0	1	3	
Leukocytosis	0	0	20	
Lymphocyte count decreased	0	0	12	
Neutropenia	0	0	8	
Leukopenia	0	0	7	
Thrombocytosis	0	0	5	
Iron deficiency anaemia	0	0	3	
Haemoglobin decreased	0	0	2	
Neutrophil count increased	0	0	2	
Red blood cell count decreased	0	0	1	
Anaemia of chronic disease	0	0	1	
Eosinophilia	0	0	1	
Haemolysis	0	0	1	
Leukostasis syndrome	0	0	1	
Immune thrombocytopenic purpura	0	0	1	
International normalised ratio increased	0	0	16	
Activated partial thromboplastin time prolonged	0	0	15	
Blood fibrinogen increased	0	0	8	
Platelet count decreased	0	0	5	
Disseminated intravascular coagulation	0	0	2	
Prothrombin time prolonged	0	0	2	
Activated partial thromboplastin time shortened	0	0	1	
Coagulation factor increased	0	0	1	
Coagulopathy	0	0	1	
Alanine aminotransferase increased	1	2	77	
Aspartate aminotransferase increased	1	2	99	
Blood alkaline phosphatase increased	0	1	70	
Blood bilirubin increased	0	1	42	
Gamma-glutamyltransferase increased	0	2	71	
Hyperbilirubinaemia	0	0	14	
Transaminases increased	0	0	8	
Blood lactate dehydrogenase increased	0	0	7	
Hepatic function abnormal	0	0	6	
Alanine aminotransferase decreased	0	0	1	
Aspartate aminotransferase decreased	0	0	1	
Blood albumin decreased	0	0	1	
Hepatic enzyme increased	0	0	1	
Liver function test increased	0	0	1	
White blood cell count decreased	0	0	8	
Neutrophil count decreased	0	0	5	
Lymphopenia	0	0	5	
Blood creatinine increased	0	0	46	
Hyperuricaemia	0	0	22	
Blood urea increased	0	0	10	
Glomerular filtration rate decreased	0	0	2	

Hypothyroidism	1	3	89	
Hyperthyroidism	0	1	30	
Blood thyroid stimulating hormone increased	0	0	16	
Blood thyroid stimulating hormone decreased	0	0	5	
Thyroxine decreased	0	0	2	
Thyroxine free decreased	0	0	2	
Thyroxine free increased	0	0	2	
Tri-iodothyronine free decreased	0	0	2	
Thyroxine increased	0	0	1	
Tri-iodothyronine decreased	0	0	1	
Tri-iodothyronine increased	0	0	1	
Hyponatraemia	1	1	91	
Hypomagnesaemia	0	1	55	
Hypercalcaemia	0	0	47	
Hyperglycaemia	0	0	32	
Hypokalaemia	0	0	60	
Hypocalcaemia	0	0	17	
Hypophosphataemia	0	0	16	
Hypertriglyceridaemia	0	0	13	
Hypoglycaemia	0	0	10	
Blood cholesterol increased	0	0	6	
Blood magnesium decreased	0	0	5	
Blood triglycerides increased	0	0	5	
Blood glucose increased	0	0	4	
Hypercholesterolaemia	0	0	4	
Blood potassium increased	0	0	3	
Blood chloride increased	0	0	2	
Blood electrolytes decreased	0	0	2	
Blood potassium decreased	0	0	2	
Hyperphosphataemia	0	0	2	
Protein total decreased	0	0	2	
Protein urine present	0	0	2	
Blood bicarbonate decreased	0	0	1	
Blood chloride decreased	0	0	1	
Blood sodium decreased	0	0	1	
Hypermagnesaemia	0	0	1	
Hypernatraemia	0	0	1	
Hypochloraemia	0	0	1	
Hypoproteinaemia	0	0	1	
Hyperkalaemia	0	0	30	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Abnormal Vital Signs Reported as TEAEs in the Dose-escalation, Dose-exploration, and Dose-expansion Phase

End point title	Number of Participants With Abnormal Vital Signs Reported as

	TEAEs in the Dose-escalation, Dose-exploration, and Dose-expansion Phase[7][8]

End point description:

Number of participants with abnormal vital signs reported as TEAEs are reported. Abnormal vital signs are defined as any abnormal finding in the vital sign parameters (body weight, body temperature, blood pressure, pulse rate, and respiratory rate). As-treated population included all participants who received any dose of study drug. Participants enrolled in the 10 mg/kg Q2W Expansion and Escalation Cohort have been summarised as a total only. This is because the safety profile of durvalumab monotherapy 10 mg/kg Q2W was manageable and generally consistent with the known safety profile of the anti-PD-L1/PD-1 drug class.

End point type	Primary

End point timeframe:

From Day 1 through 90 days after the last dose of study drug (approximately 5.25 years)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[8] - 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 1 mg/kg Q2W)	Escalation Cohort (MEDI4736 3 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: Participants				
Pyrexia	0	3	0	1
Weight decreased	0	0	0	0
Hypertension	0	1	0	1
Hypotension	0	0	0	0
Weight increased	0	0	0	0
Tachycardia	0	0	0	0
Sinus tachycardia	0	0	0	0
Arrhythmia	0	0	0	0
Sinus bradycardia	0	0	0	0
Heart rate increased	0	0	0	0
Heart rate irregular	0	0	0	0
Peak expiratory flow rate decreased	0	0	0	0

End point values	Escalation Cohort (MEDI4736 15 mg/kg Q3W)	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	Escalation/Expansion Cohort (Total MEDI4736 10 mg/kg Q2W)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	21	980	
Units: Participants				
Pyrexia	3	2	145	
Weight decreased	0	2	79	
Hypertension	0	0	31	
Hypotension	0	1	36	

Weight increased	0	0	22	
Tachycardia	0	0	19	
Sinus tachycardia	0	0	14	
Arrhythmia	0	0	3	
Sinus bradycardia	0	0	3	
Heart rate increased	0	0	1	
Heart rate irregular	0	0	1	
Peak expiratory flow rate decreased	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Change From Baseline in QT/QTc Interval in Local Electrocardiogram in the Dose-escalation, Dose-exploration, and Dose-expansion Phase

End point title	Number of Participants With Change From Baseline in QT/QTc Interval in Local Electrocardiogram in the Dose-escalation, Dose-exploration, and Dose-expansion Phase[9][10]

End point description:

Number of participants with change from baseline in notable QT/QTc interval in local electrocardiogram are reported. The data for >0 participants with notable QT/QTc interval in local electrocardiogram from baseline are reported. As-treated population included all participants who received any dose of study drug were analysed. Participants with ECG readings available were evaluable for this analysis. Participants enrolled in the 10 mg/kg Q2W Expansion and Escalation Cohort have been summarised as a total only. This is because the safety profile of durvalumab monotherapy 10 mg/kg Q2W was manageable and generally consistent with the known safety profile of the anti-PD-L1/PD-1 drug class.

End point type	Primary

End point timeframe:

From Baseline (Day 1) through 90 days after the last dose of study drug (approximately 5.25 years)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[10] - 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 1 mg/kg Q2W)	Escalation Cohort (MEDI4736 3 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: Participants				
QTcF: > 30 (msec) n=0,1,1,1,0,0,63	0	1	0	0
QTcF: > 60 (msec) n=0,1,1,1,0,0,63	0	1	0	0
QTcB: > 30 (msec) n=2,2,2,1,2,9,288	0	0	0	0
QTcB: > 60 (msec) n=2,2,2,1,2,9,288	0	0	0	0
QTcB: > 90 (msec) n=4,4,3,3,7,21,288	0	0	0	0

End point values	Escalation Cohort (MEDI4736 15 mg/kg Q3W)	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	Escalation/Expansion Cohort (Total MEDI4736 10 mg/kg Q2W)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	21	980	
Units: Participants				
QTcF: > 30 (msec) n=0,1,1,1,0,0,63	0	0	4	
QTcF: > 60 (msec) n=0,1,1,1,0,0,63	0	0	0	
QTcB: > 30 (msec) n=2,2,2,1,2,9,288	0	4	17	
QTcB: > 60 (msec) n=2,2,2,1,2,9,288	0	0	4	
QTcB: > 90 (msec) n=4,4,3,3,7,21,288	0	0	3	

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate (ORR) Assessed by Blinded Independent Central Review (BICR) in Participants With Non-squamous NSCLC who had Received 2 or More Prior Lines of Therapy in the Dose-expansion Phase

End point title	Objective Response Rate (ORR) Assessed by Blinded Independent Central Review (BICR) in Participants With Non-squamous NSCLC who had Received 2 or More Prior Lines of Therapy in the Dose-expansion Phase[11]

End point description:

The ORR assessed by BICR is reported. The ORR is defined as best overall response (BOR) of confirmed complete response (CR) or confirmed partial response (PR) based on RECIST v1.1. The CR is disappearance of all target & non-target lesions & no new lesions. A confirmed CR is 2 CRs that were separated by at least 28 days with no evidence of progression in-between. The PR is >= 30% decrease in sum of diameters of target lesions (compared to baseline) & no new nontarget lesion. A confirmed PR is 2 PRs or an un-confirmed PR and an un-confirmed CR that were separated by at least 4 wks with no evidence of progression in-between. Participants with non-squamous NSCLC in Full analysis set (FAS) population who had received 2 or more prior line of therapy were analysed. FAS population included all participants who received any dose of study drug, had measurable disease at baseline (Day 1) per BICR and were followed for at least 24 weeks by 16Oct2017.

End point type	Primary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

End point values	Expansion Non-squamous NSCLC 3L+ Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	68			
Units: Percentage of participants				
number (confidence interval 95%)	10.3 (4.2 to 20.1)			

Statistical analyses

No statistical analyses for this end point

Primary: ORR Assessed by BICR in Participants With Squamous NSCLC who had Received 1 and 2 or More Prior Lines of Therapy in the Dose-expansion Phase

End point title	ORR Assessed by BICR in Participants With Squamous NSCLC who had Received 1 and 2 or More Prior Lines of Therapy in the Dose-expansion Phase[12]

End point description:

The ORR assessed by BICR in participants with squamous NSCLC who had received 1 and 2 or more prior lines of therapy is reported. The ORR is defined as BOR of confirmed CR or confirmed PR based on RECIST v1.1. A confirmed CR is defined as two CRs that were separated by at least 28 days with no evidence of progression in-between. A confirmed PR is defined as two PRs or an un-confirmed PR and an un-confirmed CR that were separated by at least 4 weeks with no evidence of progression in-between. Participants with squamous NSCLC in FAS population who had received 1 and 2 or more prior line of therapy were analysed. FAS population included all participants who received any dose of study drug, had measurable disease at baseline (Day 1) per BICR and were followed for at least 24 weeks by 16Oct2017.

End point type	Primary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

End point values	Expansion Squamous NSCLC 3L+ Cohort	Expansion Squamous NSCLC 2L+ Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	117		
Units: Percentage of participants				
number (confidence interval 95%)	12.9 (5.7 to 23.9)	12.8 (7.4 to 20.3)		

Statistical analyses

No statistical analyses for this end point

Primary: ORR Assessed by BICR in Participants With UC Post-platinum (Programmed Cell Death Ligand [PD-L1] Status High) who had Received at Least 1 Line of Prior Therapy (2L+) in the Dose-expansion Phase

End point title	ORR Assessed by BICR in Participants With UC Post-platinum (Programmed Cell Death Ligand [PD-L1] Status High) who had Received at Least 1 Line of Prior Therapy (2L+) in the Dose-expansion Phase[13]

End point description:

The ORR assessed by BICR in participants with UC post-platinum PD-L1 status high 2L+ is reported. The ORR is defined as BOR of confirmed CR or confirmed PR based on RECIST v1.1. The CR is disappearance of all target and non-target lesions and no new lesions. A confirmed CR is 2 CRs that were separated by at least 28 days with no evidence of progression in-between. The PR is >= 30% decrease in the sum of diameters of target lesions (compared to baseline) and no new nontarget lesion. A confirmed PR is 2 PRs or an un-confirmed PR and an un-confirmed CR that were separated by at least 4 wks with no evidence of progression in-between. Participants with UC in FAS population with 2L+ post-platinum PD-L1 status high (>= 25% tumor cell membrane or >= 25% immune cell staining) were analysed. FAS population included all participants who received any dose of study drug, had measurable disease at baseline (Day 1) per BICR and were followed for at least 24 wks by 16Oct2017.

End point type	Primary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

End point values	Expansion UC PD-L1 high 2L+ Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	98			
Units: Percentage of participants				
number (confidence interval 95%)	27.6 (19.0 to 37.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Serum Concentration-time Curve up to the Last Measurable Concentration (AUClast) of MEDI4736 After the First Dose in the Dose-escalation and Dose-exploration Phase

End point title	Area Under the Serum Concentration-time Curve up to the Last Measurable Concentration (AUClast) of MEDI4736 After the First Dose in the Dose-escalation and Dose-exploration Phase[14]

End point description:

Area under the concentration-time curve from time zero to the last measurable concentration (AUClast) of MEDI4736 is reported. Pharmacokinetics (PK) evaluable population included all participants who received any dose of study drug and had at least one postdose PK concentration. Non-compartmental PK analysis was conducted using the data from dose escalation and exploration phases only.

End point type	Secondary

End point timeframe:

After the first dose between Day 0 and Day 15 (Day 1 [pre and post dose] and predose of Dose 2 for all cohorts; Days 3, 5, 10 for Cohorts 0.1mg/kg to 10 mg/kg; Days 3, 5, 10, 15 for Cohort 15 mg/kg; Day

15 for Cohort 20 mg/kg)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 1 mg/kg Q2W)	Escalation Cohort (MEDI4736 3 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: Day*µg/mL				
geometric mean (geometric coefficient of variation)	5.144 (± 45.1)	25.063 (± 65.5)	130.546 (± 20.1)	399.863 (± 21.7)

End point values	Escalation Cohort (MEDI4736 10 mg/kg Q2W)	Escalation Cohort (MEDI4736 15 mg/kg Q3W)	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	7	18	
Units: Day*µg/mL				
geometric mean (geometric coefficient of variation)	1780.152 (± 39.1)	2943.770 (± 36.3)	4501.888 (± 23.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Serum Concentration (Cmax) of MEDI4736 After the First Dose in the Dose-escalation and Dose-exploration Phase

End point title	Maximum Serum Concentration (Cmax) of MEDI4736 After the First Dose in the Dose-escalation and Dose-exploration Phase[15]

End point description:

Maximum Serum Concentration (Cmax) of MEDI4736 is reported. PK evaluable population included all participants who received any dose of study drug and had at least one postdose PK concentration. Non-compartmental PK analysis was conducted using the data from dose escalation and exploration phases only.

End point type	Secondary

End point timeframe:

After the first dose between Day 0 and Day 15 (Day 1 [pre and post dose] and predose of Dose 2 for all cohorts; Days 3, 5, 10 for Cohorts 0.1mg/kg to 10 mg/kg; Days 3, 5, 10, 15 for Cohort 15 mg/kg; Day 15 for Cohort 20 mg/kg)

Notes:

[15] - 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 1 mg/kg Q2W)	Escalation Cohort (MEDI4736 3 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: µg/mL				
geometric mean (geometric coefficient of variation)	2.780 (± 22.1)	7.969 (± 23.0)	22.773 (± 11.3)	70.807 (± 17.0)

End point values	Escalation Cohort (MEDI4736 10 mg/kg Q2W)	Escalation Cohort (MEDI4736 15 mg/kg Q3W)	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	7	18	
Units: µg/mL				
geometric mean (geometric coefficient of variation)	293.540 (± 23.4)	427.085 (± 25.5)	416.051 (± 23.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive Anti-drug Antibodies (ADA) to MEDI4736 in the Dose-escalation, Dose-exploration Phase, and Dose-expansion Phase.

End point title	Number of Participants With Positive Anti-drug Antibodies (ADA) to MEDI4736 in the Dose-escalation, Dose-exploration Phase, and Dose-expansion Phase.[16]

End point description:

Number of participants with positive ADA titer to MEDI4736 are reported. Treatment-boosted ADA is defined as baseline positive ADA titer that was boosted to a 4-fold or higher level following drug administration; persistent positive is defined as positive at >= 2 post-baseline assessments (with >= 16 weeks between first and last positive) or positive at last post-baseline assessment; and transient positive is defined as having at least one post-baseline ADA-positive assessment and not fulfilling the condition of persistent positive. ADA evaluable population included all participants who received any dose of study drug, had non-missing baseline (before Day 1) ADA, and at least one non-missing post-baseline ADA results.

End point type	Secondary

End point timeframe:

Escalation: Day1 of Dose(D)1 & D3, even numbered doses after D4; Exploration: Day1 of D1 & D2, even numbered doses after D2; Expansion: Day1 of D1, every 12 weeks since D3; all phases: till EOT, 30 days and 3 and 6 months post last dose (~5.25 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	17	257	37
Units: Participants				
Positive post-baseline	1	0	6	0
Treatment-boosted	0	0	0	0
Persistent positive	1	0	4	1
Transient positive	0	0	2	0

End point values	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	38	33
Units: Participants				
Positive post-baseline	0	1	0	1
Treatment-boosted	0	0	0	0
Persistent positive	0	1	0	1
Transient positive	0	0	0	0

End point values	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	148	17	41
Units: Participants				
Positive post-baseline	0	7	0	2
Treatment-boosted	0	1	0	0
Persistent positive	1	5	0	0
Transient positive	0	3	0	2

End point values	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	15	58	6
Units: Participants				
Positive post-baseline	1	0	2	0
Treatment-boosted	0	0	0	0
Persistent positive	1	0	1	0

Transient positive	0	0	1	0

End point values	Total Escalation/Exploration Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	45			
Units: Participants				
Positive post-baseline	4			
Treatment-boosted	0			
Persistent positive	2			
Transient positive	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Best Overall Response (BOR) Assessed by BICR in NSCLC and SCCHN cohort in the Dose-expansion Phase

End point title	Number of Participants With Best Overall Response (BOR) Assessed by BICR in NSCLC and SCCHN cohort in the Dose-expansion Phase[17]

End point description:

The BOR assessed by BICR in NSCLC and SCCHN cohort is reported. The BOR includes CR, PR, stable disease (SD), progressive disease (PD), & non-evaluable (NE). The CR is disappearance of all target & nontarget lesions & no new lesions. The PR is >= 30% decrease in the sum of diameters of target lesions (compared to baseline [BL]) & no new nontarget lesion. The PD is atleast 20% decrease in sum of diameters of target lesions (compared to baseline) and/or new lesion. The SD is neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for disease progression. The NE is when no or only a subset of lesion measurements are made at an assessment. Participants in FAS population with NSCLC and SCCHN were analysed. FAS population included all participants who received any dose of study drug, had measurable disease at BL (Day 1) per BICR and were followed for at least 24 wks by 16Oct2017.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55	275		
Units: Participants				
CR	0	3		
PR	4	39		

SD	10	80		
PD	31	110		
NE	10	43		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With BOR Assessed by Investigator in the Dose-escalation, Dose-exploration, and Dose-expansion Phase

End point title	Number of Participants With BOR Assessed by Investigator in the Dose-escalation, Dose-exploration, and Dose-expansion Phase[18]

End point description:

The BOR assessed by investigator based on RECIST v1.1 is reported. The BOR includes CR, PR, SD, PD, and NE. The CR is defined as disappearance of all target and non-target lesions and no new lesions. The PR is defined as >= 30% decrease in the sum of diameters of target lesions (compared to baseline) and no new nontarget lesion. The PD is defined at least 20% decrease in the sum of diameters of target lesions (compared to baseline) and/or new lesion. The SD is defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for disease progression. The NE is defined as either when no or only a subset of lesion measurements are made at an assessment. As-treated population included all participants who received any dose of study drug. One participant from non-SCCHN HPV positive cohort had non-evaluable disease at baseline.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	22	304	40
Units: Participants				
CR	1	1	5	0
PR	6	2	49	4
SD	14	7	102	22
PD	33	9	103	12
NE	8	2	43	2
Not applicable	0	1	0	0

End point values	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	24	51	40
Units: Participants				
CR	1	0	1	0
PR	2	1	1	1
SD	9	8	17	8
PD	5	12	21	25
NE	4	3	11	6
Not applicable	0	0	0	0

End point values	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	201	20	47
Units: Participants				
CR	0	18	0	1
PR	1	24	0	2
SD	6	45	5	18
PD	17	81	14	22
NE	7	33	1	4
Not applicable	0	0	0	0

End point values	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	62	10
Units: Participants				
CR	0	0	3	0
PR	2	2	12	3
SD	8	4	27	2
PD	8	9	15	3
NE	2	6	5	2
Not applicable	0	0	0	0

End point values	Total Escalation/Exploration Cohort			
Subject group type	Subject analysis set			
Number of subjects analysed	48			
Units: Participants				
CR	1			

PR	4			
SD	18			
PD	18			
NE	7			
Not applicable	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR) Assessed by BICR in NSCLC and SCCHN cohort in the Dose-expansion Phase

End point title	Duration of Response (DoR) Assessed by BICR in NSCLC and SCCHN cohort in the Dose-expansion Phase[19]

End point description:

DoR assessed by BICR is reported, which is duration from 1st documentation of objective response (OR) (confirmed 2 CRs [disappearance of all target and non-target lesions and no new lesions] or confirmed 2 PRs [>= 30% decrease in the sum of diameters of target lesions compared to baseline and no new non-target lesion]) to 1st documented disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. 2 CRs and/or 2 PRs should be separated by at least 28 days with no evidence of progression in-between. DoR was estimated using Kaplan-Meier method. Arbitrary number 99999 signified upper limit of CI, which was not derived due to insufficient events being observed at time of analysis. Participants in FAS population (participants who received any dose of study drug, had measurable disease at baseline (Day 1) per BICR and were followed for at least 24 wks by 16Oct2017) with NSCLC and SCCHN were analysed. DoR was analysed for those participants who achieved OR.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	42		
Units: Months				
median (confidence interval 95%)	12.37 (3.5 to 99999)	17.74 (5.6 to 38.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: DoR assessed by Investigator in the Dose-expansion Phase

End point title	DoR assessed by Investigator in the Dose-expansion Phase[20]

End point description:

The DoR assessed by investigator is reported which is defined as the duration from the first documentation of OR (confirmed 2 CRs or confirmed 2 PRs) to the first documented disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. The 2 CRs and/or 2 PRs should be separated by at least 28 days with no evidence of progression in-between. The DoR was estimated using Kaplan-Meier method. The arbitrary numbers 0.9999, 99999, & 99.999 signified the lower limit and upper limit of confidence interval, and median, respectively, which were not derived due to insufficient events being observed at the time of the analysis. As-treated population included all participants who received any dose of study drug. The DoR was analysed for those participants who achieved OR.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	54	4
Units: Months				
median (confidence interval 95%)	19.71 (1.9 to 44.0)	14.75 (12.8 to 99999)	9.95 (8.3 to 16.4)	16.20 (7.2 to 99999)

End point values	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	2	1
Units: Months				
median (confidence interval 95%)	99.999 (7.9 to 99999)	9.23 (0.9999 to 99999)	99.999 (0.9999 to 99999)	99.999 (0.9999 to 99999)

End point values	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	42	0[21]	3
Units: Months				
median (confidence interval 95%)	5.36 (0.9999 to 99999)	99.999 (14.6 to 99999)	(to)	24.87 (4.8 to 24.9)

Notes:

[21] - No participants achieved OR.

End point values	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	15	3
Units: Months				
median (confidence interval 95%)	7.92 (6.1 to 9.7)	23.51 (14.6 to 32.4)	26.91 (12.7 to 99999)	8.64 (4.4 to 16.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR) Assessed by BICR in NSCLC and SCCHN cohort in the Dose-expansion Phase

End point title	Disease Control Rate (DCR) Assessed by BICR in NSCLC and SCCHN cohort in the Dose-expansion Phase[22]

End point description:

Percentage of participants with DCR assessed by BICR is reported. The DCR is defined as a BOR of confirmed CR, confirmed PR, or SD based on RECIST v1.1. A confirmed CR is 2 CRs (disappearance of all target and non-target lesions and no new lesions) that were separated by at least 28 days with no evidence of progression in-between. A confirmed PR is 2 PRs (>= 30% decrease in sum of diameters of target lesions compared to baseline and no new non-target lesion) or an un-confirmed PR and an unconfirmed CR that were separated by at least 28 days with no evidence of progression in-between. The SD is defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for disease progression. Participants in FAS population with NSCLC and SCCHN were analysed. FAS population included all participants who received any dose of study drug, had measurable disease at baseline (Day 1) per BICR and were followed for at least 24 weeks by 16Oct2017.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55	275		
Units: Percentage of participants				
number (confidence interval 95%)	25.5 (14.7 to 39.0)	44.4 (38.4 to 50.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: DCR Assessed by Investigator in the Dose-expansion Phase

End point title	DCR Assessed by Investigator in the Dose-expansion Phase[23]

End point description:

The DCR assessed by investigator is reported. Disease control is defined as a BOR of confirmed CR, confirmed PR, or SD based on RECIST v1.1. A confirmed CR is 2 CRs (disappearance of all target and non-target lesions and no new lesions) that were separated by at least 28 days with no evidence of progression in-between. A confirmed PR is 2 PRs (>= 30% decrease in the sum of diameters of target lesions compared to baseline and no new non-target lesion) or an un-confirmed PR and an unconfirmed CR that were separated by at least 28 days with no evidence of progression in-between. The SD is defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for disease progression. The arbitrary numbers -0.9999 and 99999 signified the lower limit and upper limit of CI, which were not derived due to insufficient events being observed at the time of the analysis. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	22	302	40
Units: Percentage of participants				
number (confidence interval 95%)	33.9 (22.3 to 47.0)	45.5 (25.7 to 70.2)	51.7 (45.9 to 57.4)	65.0 (48.3 to 79.4)

End point values	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	24	51	40
Units: Percentage of participants				
number (confidence interval 95%)	57.1 (34.0 to 78.2)	37.5 (18.8 to 59.4)	37.3 (24.1 to 51.9)	22.5 (10.8 to 38.5)

End point values	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	201	20	47
Units: Percentage of participants				
number (confidence interval 95%)	22.6 (9.6 to 41.1)	43.3 (36.3 to 50.4)	0 (-0.9999 to 99999)	44.7 (30.2 to 59.9)

End point values	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	62	10
Units: Percentage of participants				
number (confidence interval 95%)	50.0 (27.2 to 72.8)	28.6 (11.3 to 52.2)	67.7 (54.7 to 79.1)	50.0 (18.7 to 81.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) Assessed by BICR in NSCLC cohort in the Dose-expansion Phase

End point title	Progression-free Survival (PFS) Assessed by BICR in NSCLC cohort in the Dose-expansion Phase[24]

End point description:

The PFS assessed by BICR in NSCLC cohort is reported. The PFS is defined as the time from the start of study treatment until the first documentation of disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. The PD is defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study; the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered PD. The PFS was estimated using Kaplan-Meier method. Participants in As-treated population with NSCLC were analysed. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	304			
Units: Percentage of participants				
median (confidence interval 95%)	2.1 (1.5 to 2.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: PFS Assessed by BICR in SCCHN cohort in the Dose-expansion Phase

End point title	PFS Assessed by BICR in SCCHN cohort in the Dose-expansion Phase[25]

End point description:

The PFS assessed by BICR in SCCHN cohort is reported. The PFS is defined as the time from the start of study treatment until the first documentation of disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. The PD is defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study; the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered PD. The PFS was estimated using Kaplan-Meier method. Participants in FAS population with SCCHN were analyzed. FAS population included all participants who received any dose of study drug, had measurable disease at baseline (Day 1) per BICR and were followed for at least 24 weeks by 16Oct2017.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	62			
Units: Percentage of participants				
median (confidence interval 95%)	1.4 (1.3 to 1.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: PFS Assessed by Investigator in the Dose-expansion Phase

End point title	PFS Assessed by Investigator in the Dose-expansion Phase[26]

End point description:

The PFS assessed by the investigator is reported. The PFS is defined as the time from the start of study treatment until the first documentation of disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. The PD is defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study; the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered PD. The PFS was estimated using Kaplan-Meier method. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	22	302	40
Units: Months				
median (confidence interval 95%)	1.4 (1.4 to 1.6)	1.5 (1.2 to 5.6)	2.6 (1.9 to 3.2)	2.7 (1.4 to 5.3)

End point values	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	24	51	40
Units: Months				
median (confidence interval 95%)	2.8 (1.2 to 9.1)	1.4 (1.3 to 4.6)	1.4 (1.2 to 2.4)	1.3 (1.2 to 1.6)

End point values	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	201	20	47
Units: Months				
median (confidence interval 95%)	1.5 (1.3 to 1.7)	1.8 (1.4 to 2.6)	1.4 (1.2 to 2.3)	1.8 (1.4 to 2.7)

End point values	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion MSI-high Cancer Cohort (MEDI4736 10	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)

			mg/kg Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	62	10
Units: Months				
median (confidence interval 95%)	2.6 (1.4 to 3.0)	1.5 (0.9 to 1.8)	5.4 (2.9 to 11.1)	2.2 (0.7 to 5.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) in the Dose-Expansion Phase

End point title	Overall Survival (OS) in the Dose-Expansion Phase[27]

End point description:

The OS is defined as the time from the start of study treatment until death due to any cause. The OS was estimated using Kaplan-Meier method. The arbitrary numbers 99999 and 99.999 signified the data for upper limit of confidence interval and median, respectively, which were not derived due to insufficient events being observed at the time of the analysis. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN HPV+ Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	22	304	40
Units: Months				
median (confidence interval 95%)	8.4 (5.7 to 12.3)	11.6 (3.0 to 22.8)	12.4 (9.3 to 15.2)	13.2 (6.3 to 23.0)

End point values	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	24	51	40
Units: Months				
median (confidence interval 95%)	99.999 (15.1 to 99999)	8.4 (4.5 to 14.3)	4.9 (2.6 to 9.1)	5.5 (3.5 to 16.8)

End point values	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	201	20	47
Units: Months				
median (confidence interval 95%)	5.7 (4.8 to 8.0)	10.5 (6.9 to 15.7)	10.0 (6.2 to 13.0)	11.1 (8.2 to 16.6)

End point values	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	62	10
Units: Months				
median (confidence interval 95%)	15.8 (8.1 to 23.3)	4.8 (1.3 to 10.4)	24.1 (12.4 to 37.1)	16.1 (0.9 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: ORR Assessed by BICR in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point title	ORR Assessed by BICR in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point description:

The ORR assessed by BICR in UC cohort is reported. The ORR is BOR of confirmed CR (2 CRs separated by at least 28 days with no evidence of progression in-between) or confirmed PR (2 PRs or an un-confirmed PR & an un-confirmed CR separated by at least 4 wks with no evidence of progression in-between) based on RECIST v1.1. The CR is disappearance of all target and non-target lesions and no new lesions. The PR is >= 30% decrease in sum of diameters of target lesions (compared to baseline) and no new nontarget lesion. The UC cohort participants with PD-L1 status as low/negative (<25% tumor cell membrane and <25% immune cell staining), total (PD-L1 high, PD-L1 low/negative, and PD-L1 unknown), and high (>= 25% tumor cell membrane or >=25% immune cell staining) included in the FAS population were analysed. FAS population included all participants who received any dose of study drug, had measurable disease at baseline (Day 1) per BICR and were followed for at least 24 weeks by 16Oct2017.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC Total Cohort	Expansion UC PD-L1 high Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	85	199	101	
Units: Percentage of participants				
number (confidence interval 95%)	5.9 (1.9 to 13.2)	17.6 (12.6 to 23.6)	27.7 (19.3 to 37.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: ORR Assessed by Investigator in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point title	ORR Assessed by Investigator in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point description:

The ORR assessed by the investigator in UC cohort is reported. The ORR is defined as BOR of confirmed CR or confirmed PR based on RECIST v1.1. A confirmed CR is defined as two CRs that were separated by at least 28 days with no evidence of progression in-between. The PR is defined as >= 30% decrease in the sum of diameters of target lesions (compared to baseline) and no new nontarget lesion. A confirmed PR is defined as two PRs or an un-confirmed PR and an un-confirmed CR that were separated by at least 4 weeks with no evidence of progression in-between. The UC cohort participants with PD-L1 status as low/negative (<25% tumor cell membrane and <25% immune cell staining), total (PD-L1 high, PD-L1 low/negative, and PD-L1 unknown), and high (>= 25% tumor cell membrane or >=25% immune cell staining) included in the As-treated population were analysed. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC Total Cohort	Expansion UC PD-L1 high Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	86	201	102	
Units: Percentage of participants				
number (confidence interval 95%)	7.0 (2.6 to 14.6)	20.9 (15.5 to 27.2)	33.3 (24.3 to 43.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: DoR Assessed by BICR in UC Cohort (PD-L1 low/Negative, Total, and PD-

L1 high) in the Dose-expansion Phase

End point title	DoR Assessed by BICR in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point description:

The DoR assessed by BICR in UC cohort is reported. The DoR is the duration from the first documentation of OR (confirmed 2 CRs or confirmed 2 PRs) to the first documented disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. The 2 CRs and/or 2 PRs should be separated by at least 28 days with no evidence of progression in-between. The arbitrary numbers 99999 & 99.999 signified upper limit of confidence interval and median, respectively, which were not derived due to insufficient events being observed at the time of the analysis. The DoR was estimated using Kaplan-Meier method. The UC cohort participants with PD-L1 status as low/negative, total, and high included in the FAS population (participants who received any dose of study drug, had measurable disease at baseline (Day 1) per BICR and were followed for at least 24 wks by 16Oct2017) were analysed. The DoR was analysed for those participants who achieved OR.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC Total Cohort	Expansion UC PD-L1 high Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	5	35	28	
Units: Months				
median (confidence interval 95%)	12.25 (8.6 to 99999)	99.999 (16.0 to 99999)	99.999 (16.0 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: DoR Assessed by Investigator in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point title	DoR Assessed by Investigator in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point description:

The DoR assessed by investigator in UC cohort is reported. The DoR is the duration from the first documentation of OR (confirmed 2 CRs or confirmed 2 PRs) to the first documented disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. The 2 CRs and/or 2 PRs should be separated by at least 28 days with no evidence of progression in-between. The DoR was estimated using Kaplan-Meier method. The arbitrary number 99999 signified upper limit of CI, which was not derived due to insufficient events being observed at the time of the analysis. The UC cohort participants with PD-L1 status as low/negative (<25% tumor cell membrane and <25% immune cell staining), total (PD-L1 high, PD-L1 low/negative, and PD-L1 unknown), and high (>= 25% tumor cell membrane or >=25% immune cell staining) included in the As-treated population (all participants who received any dose of study drug) were analysed. The DoR was analysed for those participants who achieved OR.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC Total Cohort	Expansion UC PD-L1 high Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	6	42	34	
Units: Months				
median (confidence interval 95%)	14.82 (6.9 to 99999)	19.71 (14.6 to 99999)	99.999 (12.3 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: DCR Assessed by BICR in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point title	DCR Assessed by BICR in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point description:

The DCR assessed by BICR in UC cohort is reported, which is defined as BOR of confirmed CR (2 CRs [disappearance of all target and nontarget lesions and no new lesions]), confirmed PR (2 PRs [>= 30% decrease in sum of diameters of target lesions compared to baseline and no new nontarget lesion] or an unconfirmed PR and an unconfirmed CR), or SD (neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for disease progression) based on RECIST v1.1. 2 CRs and/or 2 PRs should be separated by at least 28 days with no evidence of progression in-between. The UC cohort participants with PD-L1 status as low/negative, total, and high included in the FAS population (all participants who received any dose of study drug, had measurable disease at baseline (Day 1) per BICR and were followed for at least 24 wks by 16Oct2017) were analysed.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC Total Cohort	Expansion UC PD-L1 high Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	85	199	101	
Units: Percentage of participants				
number (confidence interval 95%)	21.2 (13.1 to 31.4)	35.2 (28.6 to 42.2)	43.6 (33.7 to 53.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: DCR Assessed by Investigator in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point title	DCR Assessed by Investigator in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point description:

Percentage of participants with DCR assessed by investigator in UC cohort is reported. The DCR is BOR of confirmed CR, (2 CRs [disappearance of all target and nontarget lesions and no new lesions]), confirmed PR (2 PRs [>= 30% decrease in sum of diameters of target lesions compared to baseline and no new nontarget lesion] or an unconfirmed PR and an unconfirmed CR), or SD (neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for disease progression) based on RECIST v1.1. 2 CRs and/or 2 PRs should be separated by at least 28 days with no evidence of progression in-between. The UC cohort participants with PD-L1 status as low/negative (<25% tumor cell membrane and <25% immune cell staining), total (PD-L1 high, PD-L1 low/negative, and PD-L1 unknown) & high (>= 25% tumor cell membrane or >=25% immune cell staining) included in the As-treated population were analysed. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC Total Cohort	Expansion UC PD-L1 high Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	86	201	102	
Units: Percentage of participants				
number (confidence interval 95%)	30.2 (20.8 to 41.1)	43.3 (36.3 to 50.4)	53.9 (43.8 to 63.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: PFS Assessed by BICR in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point title	PFS Assessed by BICR in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point description:

The PFS assessed by BICR in UC cohort is reported. The PFS is defined as the time from the start of study treatment until the first documentation of disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. The PD is defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study; the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered PD. The PFS was estimated using Kaplan-Meier method. The UC cohort participants with PD-L1 status as low/negative (<25% tumor cell membrane and <25% immune cell staining), total (PD-L1 high, PD-L1 low/negative, and PD-L1 unknown), and high (>= 25% tumor cell membrane or >=25% immune cell staining) included in the As-treated population were analysed. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC Total Cohort	Expansion UC PD-L1 high Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	86	201	102	
Units: Months				
median (confidence interval 95%)	1.4 (1.3 to 1.5)	1.5 (1.4 to 1.8)	1.9 (1.4 to 2.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: PFS Assessed by Investigator in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point title	PFS Assessed by Investigator in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point description:

The PFS assessed by the investigator in UC cohort is reported. The PFS is defined as the time from the start of study treatment until the first documentation of disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. The PD is defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study; the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered PD. The PFS was estimated using Kaplan-Meier method. The UC cohort participants with PD-L1 status as low/negative (<25% tumor cell membrane and <25% immune cell staining), total (PD-L1 high, PD-L1 low/negative, and PD-L1 unknown), and high (>= 25% tumor cell membrane or >=25% immune cell staining) included in the As-treated population were analysed. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC Total Cohort	Expansion UC PD-L1 high Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	86	201	102	
Units: Months				
median (confidence interval 95%)	1.4 (1.4 to 1.7)	1.8 (1.4 to 2.6)	2.8 (1.8 to 3.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: OS in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point title	OS in UC Cohort (PD-L1 low/Negative, Total, and PD-L1 high) in the Dose-expansion Phase

End point description:

The OS in UC cohort is reported. The OS is defined as the time from the start of study treatment until death due to any cause. The OS was estimated using Kaplan-Meier method. The arbitrary number 99999 signified upper limit of confidence interval which was not derived due to insufficient events being observed at the time of the analysis. The UC cohort participants with PD-L1 status as low/negative (<25% tumor cell membrane and <25% immune cell staining), total (PD-L1 high, PD-L1 low/negative, and PD-L1 unknown), and high (>= 25% tumor cell membrane or >=25% immune cell staining) included in the As-treated population were analysed. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC Total Cohort	Expansion UC PD-L1 high Cohort	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	86	201	102	
Units: Months				
median (confidence interval 95%)	4.8 (3.3 to 8.1)	10.5 (6.9 to 15.7)	19.8 (9.3 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adjusted Comparison of PFS by PD-L1 status in UC Cohort in the Dose-expansion Phase

End point title	Adjusted Comparison of PFS by PD-L1 status in UC Cohort in the Dose-expansion Phase

End point description:

The PFS by PD-L1 status in UC cohort is reported. The PFS estimates are adjusted for baseline eastern cooperative oncology group (ECOG), smoking status, race, gender, age, previous lines of therapy, and liver metastasis. 95% CIs based on log (-log(survival)). The PFS is the time from the start of study treatment until first documentation of disease progression based on RECIST v1.1 or death due to any cause, whichever occurred first. PD is defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study; the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered PD. The PFS was estimated using Kaplan-Meier method. The UC cohort participants with PD-L1 status as high (>= 25% tumor cell membrane or >=25% immune cell staining) and low/negative (<25% tumor cell membrane and <25% immune cell staining) included in the As-treated population were analysed.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC PD-L1 high Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	39	61		
Units: Months				
median (confidence interval 95%)	1.5 (1.4 to 2.4)	2.6 (1.4 to 3.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Expansion UC PD-L1 high Cohort v Expansion UC PD-L1 low/Negative Cohort
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.016
Method	Regression, Cox

Secondary: Adjusted Comparison of OS by PD-L1 status in UC Cohort in the Dose-expansion Phase

End point title	Adjusted Comparison of OS by PD-L1 status in UC Cohort in the Dose-expansion Phase

End point description:

The OS by PD-L1 status in UC cohort is reported. The OS estimates are adjusted for baseline ECOG, smoking status, race, gender, age, previous lines of therapy, and liver metastasis. 95% CIs based on log (-log(survival)). The OS is defined as the time from the start of study treatment until death due to any cause. The OS was estimated using Kaplan-Meier method. The arbitrary number 99999 signified upper limit of confidence interval which was not derived due to insufficient events being observed at the time of the analysis. The UC cohort participants with PD-L1 status as high (>= 25% tumor cell membrane or >=25% immune cell staining) and low/negative (<25% tumor cell membrane and <25% immune cell staining) included in the As-treated population were analysed. As-treated population included all participants who received any dose of study drug.

End point type	Secondary

End point timeframe:

From Day 1 through disease progression, study withdrawal, or initiation of another anticancer therapy, whichever occurred first (approximately 5.25 years)

End point values	Expansion UC PD-L1 low/Negative Cohort	Expansion UC PD-L1 high Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	39	61		
Units: Months				
median (confidence interval 95%)	3.4 (2.4 to 14.3)	18.4 (7.8 to 99999)		

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Expansion UC PD-L1 high Cohort v Expansion UC PD-L1 low/Negative Cohort
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0046
Method	Regression, Cox

Adverse events information

Timeframe for reporting adverse events:

From Day 1 through 90 days after the last dose of study drug (approximately 5.25 years)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)

Reporting group description:

Participants received intravenous (IV) infusion of MEDI4736 0.1 mg/kg every 2 weeks (Q2W) in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 0.3 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 3 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 3 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 1 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 1 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 15 mg/kg Q3W)

Reporting group description:

Participants received IV infusion of MEDI4736 15 mg/kg every 3 weeks (Q3W) in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Escalation Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-escalation phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Exploration Cohort (MEDI4736 20 mg/kg Q4W)

Reporting group description:

Participants received IV infusion of MEDI4736 20 mg/kg every 4 weeks (Q4W) in the dose-exploration phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with squamous cell carcinoma of the head and neck (SCCHN) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of

consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion Non-SCCHN Cohort HPV+ (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with non-SCCHN human papilloma virus positive (Non-SCCHN HPV+) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with non-small-cell lung cancer (NSCLC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with hepatocellular carcinoma (HCC Total) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with uveal melanoma (UM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with advance cutaneous melanoma (ACM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with gastroesophageal (GEC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with triple-negative breast cancer (TNBC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with urothelial carcinoma (UC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with pancreatic adenocarcinoma (PAC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with glioblastoma multiforme (GBM) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose- expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of

alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with soft- tissue sarcoma (STS) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with ovarian cancer (OC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with microsatellite instability (MSI)-high cancer received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with small-cell lung cancer (SCLC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose-expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Reporting group title	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)

Reporting group description:

Participants with nasopharyngeal carcinoma (NPC) received IV infusion of MEDI4736 10 mg/kg Q2W in the dose- expansion phase for maximum of 12 months or until confirmed progressive disease, initiation of alternative cancer therapy, unacceptable toxicity, withdrawal of consent, or development of other reason for treatment discontinuation, whichever occurred first.

Serious adverse events	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 3 mg/kg Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	1 / 3 (33.33%)
number of deaths (all causes)	4	2	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA PANCREAS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ANAL CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLADDER CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLADDER CANCER STAGE IV			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER METASTATIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANCER PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVIX CARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOROID MELANOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL ADENOCARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROOESOPHAGEAL CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GLIOBLASTOMA MULTIFORME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRAOCULAR MELANOMA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG NEOPLASM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT MELANOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT NEOPLASM OF RENAL PELVIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTASES TO BLADDER			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC CARCINOMA OF THE BLADDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC GASTRIC CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NASOPHARYNGEAL CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEOPLASM SWELLING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
NON-SMALL CELL LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL ADENOCARCINOMA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL CANCER METASTATIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL CARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ONCOLOGIC COMPLICATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATIC CARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATIC CARCINOMA METASTATIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATIC CARCINOMA STAGE IV			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARANEOPLASTIC SYNDROME			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL CELL LUNG CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE SARCOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF HEAD AND NECK			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF LUNG			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF PHARYNX			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF			

THE HYPOPHARYNX			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CANCER OF THE RENAL PELVIS AND URETER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA METASTATIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA RECURRENT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIPLE NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR ASSOCIATED FEVER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR FLARE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

TUMOUR PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VULVAL CANCER METASTATIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
EMBOLISM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPERIOR VENA CAVA SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR OCCLUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENA CAVA THROMBOSIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHILLS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH			

DETERIORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHIAL OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

HAEMOPTYSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGOBRONCHIAL FISTULA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PHARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURITIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY VENOUS THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL STENOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
ANXIETY			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE MALFUNCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE OCCLUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL FRACTURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGINA PECTORIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FLUTTER			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC ARREST			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC TAMPONADE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIOVASCULAR DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC CARDIOMYOPATHY			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALPITATIONS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIFASCICULAR BLOCK			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
APHASIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL GANGLIA INFARCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CAUDA EQUINA SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSARTHRIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL PARALYSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA HOMONYMOUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIPARESIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDROCEPHALUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC NEUROPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC STROKE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MIGRAINE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MONOPARESIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARAESTHESIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARTIAL SEIZURES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL SENSORY NEUROPATHY			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEIZURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL CORD COMPRESSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL CORD OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIGEMINAL NEURALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISSEMINATED INTRAVASCULAR COAGULATION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE THROMBOCYTOPENIC PURPURA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPH NODE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN LOWER			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS ISCHAEMIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLONIC FISTULA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL OBSTRUCTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL STENOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROVESICAL FISTULA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAECALOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC PERFORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATEMESIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEUS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL ISCHAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL PERFORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL PERFORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICES OESOPHAGEAL			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
AUTOIMMUNE HEPATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC HEPATIC FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FUNCTION ABNORMAL			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC VEIN THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOBILIARY DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
AZOTAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDROURETER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROTEINURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY BLADDER POLYP			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTHYROIDISM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEROID WITHDRAWAL SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

FLANK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GROIN PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYMYALGIA RHEUMATICA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABDOMINAL ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BARTHOLINITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYSIPELAS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED FISTULA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KIDNEY INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECROTISING FASCIITIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOMYELITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY TUBERCULOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT CANDIDIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERLIPASAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METABOLIC ACIDOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Escalation Cohort (MEDI4736 1 mg/kg Q2W)	Escalation Cohort (MEDI4736 15 mg/kg Q3W)	Escalation Cohort (MEDI4736 10 mg/kg Q2W)

Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	3 / 6 (50.00%)
number of deaths (all causes)	0	4	6
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA PANCREAS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CANCER STAGE IV			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER METASTATIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANCER PAIN			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVIX CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOROID MELANOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL ADENOCARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROOESOPHAGEAL CANCER			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GLIOBLASTOMA MULTIFORME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRAOCULAR MELANOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 ADENOCARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CANCER METASTATIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 NEOPLASM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 MELANOMA			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (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 NEOPLASM OF RENAL PELVIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PLEURAL EFFUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTASES TO BLADDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC CARCINOMA OF THE BLADDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC GASTRIC CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NASOPHARYNGEAL CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEOPLASM SWELLING			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
NON-SMALL CELL LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 ADENOCARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CANCER METASTATIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ONCOLOGIC COMPLICATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CARCINOMA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CARCINOMA METASTATIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CARCINOMA STAGE IV			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARANEOPLASTIC SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CELL LUNG CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE SARCOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 OF HEAD AND NECK			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 OF LUNG			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 OF PHARYNX			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 OF THE HYPOPHARYNX			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CANCER OF THE RENAL PELVIS AND URETER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA METASTATIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA RECURRENT			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIPLE NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 ASSOCIATED FEVER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 FLARE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VULVAL CANCER METASTATIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
EMBOLISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPERIOR VENA CAVA SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 OCCLUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
ASTHENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHILLS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (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
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (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
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGOBRONCHIAL FISTULA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 HAEMORRHAGE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (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
PLEURITIC PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 VENOUS THROMBOSIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL STENOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
ANXIETY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 MALFUNCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE OCCLUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
CONTUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 COMPRESSION FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 FRACTURE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGINA PECTORIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FLUTTER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (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
CARDIAC TAMPONADE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CARDIOMYOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALPITATIONS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIFASCICULAR BLOCK			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
APHASIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL GANGLIA INFARCTION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CAUDA EQUINA SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSARTHRIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA HOMONYMOUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 STROKE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MIGRAINE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MONOPARESIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 OEDEMA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIGEMINAL NEURALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 THROMBOCYTOPENIC PURPURA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPH NODE PAIN			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
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 LOWER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 UPPER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLONIC FISTULA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL STENOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROVESICAL FISTULA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAECALOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PERFORATION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 HAEMORRHAGE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICES OESOPHAGEAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
AUTOIMMUNE HEPATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 HEPATIC FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 VEIN THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 DISEASE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			
ERYTHEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
AZOTAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDROURETER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 BLADDER POLYP			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTHYROIDISM			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEROID WITHDRAWAL SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GROIN PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CHEST PAIN			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYMYALGIA RHEUMATICA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 INFECTION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BARTHOLINITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 COLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED FISTULA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KIDNEY INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECROTISING FASCIITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 WOUND INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 TUBERCULOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 CANDIDIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (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
FAILURE TO THRIVE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERLIPASAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (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
HYPOPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
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	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN Cohort HPV+ (MEDI4736 10 mg/kg Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 21 (61.90%)	30 / 62 (48.39%)	16 / 22 (72.73%)
number of deaths (all causes)	17	42	17
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
ADENOCARCINOMA PANCREAS			

subjects affected / exposed	2 / 21 (9.52%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
ANAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	3 / 22 (13.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
BLADDER CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CANCER STAGE IV			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANCER PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVIX CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
CHOROID MELANOMA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL ADENOCARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROOESOPHAGEAL CANCER			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
GLIOBLASTOMA MULTIFORME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR CARCINOMA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRAOCULAR MELANOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 ADENOCARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 NEOPLASM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 MELANOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 NEOPLASM OF RENAL PELVIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 PLEURAL EFFUSION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTASES TO BLADDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC CARCINOMA OF THE BLADDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC GASTRIC CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NASOPHARYNGEAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEOPLASM SWELLING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
NON-SMALL CELL LUNG CANCER METASTATIC			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 ADENOCARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ONCOLOGIC COMPLICATION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
OVARIAN CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CARCINOMA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
PANCREATIC CARCINOMA METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CARCINOMA STAGE IV			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARANEOPLASTIC SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CELL LUNG CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE SARCOMA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SQUAMOUS CELL CARCINOMA OF HEAD AND NECK			
subjects affected / exposed	0 / 21 (0.00%)	6 / 62 (9.68%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 5	0 / 0
SQUAMOUS CELL CARCINOMA OF LUNG			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 OF PHARYNX			

subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
SQUAMOUS CELL CARCINOMA OF THE HYPOPHARYNX			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
TRANSITIONAL CELL CANCER OF THE RENAL PELVIS AND URETER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA RECURRENT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIPLE NEGATIVE BREAST CANCER			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
TUMOUR ASSOCIATED FEVER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 FLARE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VULVAL CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
EMBOLISM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
SUPERIOR VENA CAVA SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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 OCCLUSION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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			
ASTHENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHILLS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
FATIGUE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
PYREXIA			

subjects affected / exposed	1 / 21 (4.76%)	3 / 62 (4.84%)	0 / 22 (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
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
BRONCHIAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	4 / 62 (6.45%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (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
HYPOXIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGOBRONCHIAL FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
PLEURAL EFFUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURITIC PAIN			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 VENOUS THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 FAILURE			

subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
TRACHEAL STENOSIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 MALFUNCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE OCCLUSION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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			
CONTUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 COMPRESSION FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGINA PECTORIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
ATRIAL FLUTTER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 TAMPONADE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CARDIOMYOPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
MYOCARDITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALPITATIONS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIFASCICULAR BLOCK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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			
APHASIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL GANGLIA INFARCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CAUDA EQUINA SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	1 / 21 (4.76%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
COGNITIVE DISORDER			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSARTHRIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA HOMONYMOUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 STROKE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MIGRAINE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MONOPARESIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
SEIZURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIGEMINAL NEURALGIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 THROMBOCYTOPENIC PURPURA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
LYMPH NODE PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (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
THROMBOCYTOSIS			

subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	2 / 21 (9.52%)	0 / 62 (0.00%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 UPPER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	3 / 22 (13.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLONIC FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL STENOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROVESICAL FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAECALOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 GASTROINTESTINAL HAEMORRHAGE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL PERFORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICES OESOPHAGEAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
AUTOIMMUNE HEPATITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC HEPATIC FAILURE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 VEIN THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 DISEASE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 INJURY			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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			
ERYTHEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
AZOTAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDROURETER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC OBSTRUCTION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 BLADDER POLYP			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTHYROIDISM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEROID WITHDRAWAL SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BACK PAIN			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GROIN PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
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 PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOSITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECK PAIN			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 IN EXTREMITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYMYALGIA RHEUMATICA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BARTHOLINITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 COLITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
DIVERTICULITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED FISTULA			

subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
KIDNEY INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECROTISING FASCIITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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	2 / 21 (9.52%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 TUBERCULOSIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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	1 / 21 (4.76%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
SEPTIC SHOCK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 CANDIDIASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
DEHYDRATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (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
HYPERGLYCAEMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERLIPASAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (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
HYPOPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
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	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	163 / 304 (53.62%)	24 / 40 (60.00%)	12 / 24 (50.00%)
number of deaths (all causes)	208	30	19
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA PANCREAS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CANCER STAGE IV			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER METASTATIC			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANCER PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVIX CARCINOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOROID MELANOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
COLON CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL ADENOCARCINOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL CANCER			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROOESOPHAGEAL CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GLIOBLASTOMA MULTIFORME			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 304 (0.00%)	7 / 40 (17.50%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 6	0 / 0
INTRAOCULAR MELANOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
LUNG ADENOCARCINOMA			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
LUNG CANCER METASTATIC			

subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
LUNG NEOPLASM			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
LUNG NEOPLASM MALIGNANT			
subjects affected / exposed	13 / 304 (4.28%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 12	0 / 0	0 / 0
MALIGNANT MELANOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 NEOPLASM OF RENAL PELVIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 PLEURAL EFFUSION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTASES TO BLADDER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC CARCINOMA OF THE BLADDER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC GASTRIC CANCER			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
NASOPHARYNGEAL CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEOPLASM SWELLING			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
NON-SMALL CELL LUNG CANCER			
subjects affected / exposed	47 / 304 (15.46%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 55	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 43	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER METASTATIC			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
OESOPHAGEAL ADENOCARCINOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CANCER METASTATIC			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CARCINOMA			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ONCOLOGIC COMPLICATION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CARCINOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CARCINOMA METASTATIC			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CARCINOMA STAGE IV			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARANEOPLASTIC SYNDROME			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CELL LUNG CANCER			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE SARCOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 OF HEAD AND NECK			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 OF LUNG			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF PHARYNX			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 OF THE HYPOPHARYNX			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CANCER OF THE RENAL PELVIS AND URETER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA METASTATIC			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA RECURRENT			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIPLE NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 ASSOCIATED FEVER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 FLARE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 PAIN			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
VULVAL CANCER METASTATIC			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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			

EMBOLISM			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
HYPOTENSION			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (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
SUPERIOR VENA CAVA SYNDROME			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 OCCLUSION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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			

ASTHENIA			
subjects affected / exposed	1 / 304 (0.33%)	2 / 40 (5.00%)	0 / 24 (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
CHEST PAIN			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
CHILLS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
FATIGUE			
subjects affected / exposed	4 / 304 (1.32%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	3 / 304 (0.99%)	3 / 40 (7.50%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 0
MALAISE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (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
OEDEMA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
OEDEMA PERIPHERAL			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
PYREXIA			
subjects affected / exposed	3 / 304 (0.99%)	2 / 40 (5.00%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
BRONCHIAL OBSTRUCTION			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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 OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	5 / 304 (1.64%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
DYSPNOEA			
subjects affected / exposed	23 / 304 (7.57%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 24	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (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
HYPOXIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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

OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
OESOPHAGOBRONCHIAL FISTULA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
PHARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	9 / 304 (2.96%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURITIC PAIN			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (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
PNEUMONIA ASPIRATION			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	3 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (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
PULMONARY EMBOLISM			

subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
PULMONARY HAEMORRHAGE			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
PULMONARY VENOUS THROMBOSIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
RESPIRATORY FAILURE			
subjects affected / exposed	8 / 304 (2.63%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 0
TRACHEAL STENOSIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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			
ANXIETY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
MENTAL STATUS CHANGES			

subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 MALFUNCTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE OCCLUSION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
BLOOD ALKALINE PHOSPHATASE INCREASED			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	1 / 24 (4.17%)
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 ELECTROLYTES DECREASED			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
FEMUR FRACTURE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
HIP FRACTURE			
subjects affected / exposed	1 / 304 (0.33%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 COMPRESSION FRACTURE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 FRACTURE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGINA PECTORIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (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
ATRIAL FLUTTER			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CARDIAC ARREST			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
CARDIAC FAILURE			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 TAMPONADE			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 CARDIOMYOPATHY			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
MYOCARDIAL INFARCTION			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
MYOCARDITIS			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALPITATIONS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
PERICARDIAL EFFUSION			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUS TACHYCARDIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIFASCICULAR BLOCK			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
APHASIA			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
ATAXIA			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL GANGLIA INFARCTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CAUDA EQUINA SYNDROME			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
COGNITIVE DISORDER			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
DIZZINESS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSARTHRIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (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
HEADACHE			

subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
HEMIANOPIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
HEMIANOPIA HOMONYMOUS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	1 / 40 (2.50%)	0 / 24 (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
HYDROCEPHALUS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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 NEUROPATHY			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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 STROKE			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
MIGRAINE			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
MONOPARESIS			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
SPINAL CORD COMPRESSION			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 OEDEMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
TRIGEMINAL NEURALGIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
IMMUNE THROMBOCYTOPENIC PURPURA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOCYTOSIS			

subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
LYMPH NODE PAIN			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOSIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 PAIN			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 UPPER			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			

subjects affected / exposed	1 / 304 (0.33%)	2 / 40 (5.00%)	0 / 24 (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
COLITIS			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	4 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS ISCHAEMIC			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
COLONIC FISTULA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
DIARRHOEA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
DUODENAL OBSTRUCTION			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
DUODENAL STENOSIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			

subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROVESICAL FISTULA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAECALOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
HAEMATEMESIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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 OBSTRUCTION			

subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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 PERFORATION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
PANCREATITIS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
PROCTALGIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTITIS			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
SMALL INTESTINAL PERFORATION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
VARICES OESOPHAGEAL			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
VOMITING			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (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
Hepatobiliary disorders			
AUTOIMMUNE HEPATITIS			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
CHOLELITHIASIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 HEPATIC FAILURE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	1 / 40 (2.50%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
HEPATIC FUNCTION ABNORMAL			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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 VEIN THROMBOSIS			

subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
HEPATOBILIARY DISEASE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
LIVER INJURY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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			
ERYTHEMA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
AZOTAEMIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDROURETER			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
PROTEINURIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 BLADDER POLYP			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
HYPERTHYROIDISM			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEROID WITHDRAWAL SYNDROME			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
BACK PAIN			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (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
FLANK PAIN			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
GROIN PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			

subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
MYOSITIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECK PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 IN EXTREMITY			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
PATHOLOGICAL FRACTURE			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
POLYMYALGIA RHEUMATICA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 ABSCESS			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BARTHOLINITIS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
BRONCHITIS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
CELLULITIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 COLITIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (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
ERYSIPELAS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
INFECTED FISTULA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KIDNEY INFECTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECROTISING FASCIITIS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
OSTEOMYELITIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			

subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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	21 / 304 (6.91%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	2 / 29	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 TUBERCULOSIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (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
SEPSIS			
subjects affected / exposed	6 / 304 (1.97%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
SEPTIC SHOCK			

subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
SINUSITIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (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
URINARY TRACT CANDIDIASIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
UROSEPSIS			
subjects affected / exposed	1 / 304 (0.33%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metabolism and nutrition disorders			
DECREASED APPETITE			

subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (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
DEHYDRATION			
subjects affected / exposed	3 / 304 (0.99%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAILURE TO THRIVE			
subjects affected / exposed	1 / 304 (0.33%)	1 / 40 (2.50%)	0 / 24 (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
HYPERCALCAEMIA			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (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
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERLIPASAEMIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (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
HYPOPHAGIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
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	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 21 (33.33%)	26 / 51 (50.98%)	20 / 40 (50.00%)
number of deaths (all causes)	8	42	23
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF THE CERVIX			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA PANCREAS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CANCER STAGE IV			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANCER PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVIX CARCINOMA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOROID MELANOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL ADENOCARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 21 (0.00%)	4 / 51 (7.84%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 0
GASTROOESOPHAGEAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
GLIOBLASTOMA MULTIFORME			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRAOCULAR MELANOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 ADENOCARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 NEOPLASM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 MELANOMA			
subjects affected / exposed	2 / 21 (9.52%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
MALIGNANT NEOPLASM OF RENAL PELVIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 PLEURAL EFFUSION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
METASTASES TO BLADDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC CARCINOMA OF THE BLADDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC GASTRIC CANCER			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	2 / 21 (9.52%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
NASOPHARYNGEAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEOPLASM SWELLING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 ADENOCARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
OESOPHAGEAL CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
OESOPHAGEAL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	3 / 51 (5.88%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
ONCOLOGIC COMPLICATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CARCINOMA METASTATIC			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CARCINOMA STAGE IV			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARANEOPLASTIC SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
PROSTATE CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CELL LUNG CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE SARCOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 OF HEAD AND NECK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 OF LUNG			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 OF PHARYNX			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 OF THE HYPOPHARYNX			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CANCER OF THE RENAL PELVIS AND URETER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA RECURRENT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIPLE NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2

TUMOUR ASSOCIATED FEVER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 FLARE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
VULVAL CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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			
EMBOLISM			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
HAEMATOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPERIOR VENA CAVA SYNDROME			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 OCCLUSION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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			
ASTHENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHILLS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
FATIGUE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
MALAISE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	2 / 51 (3.92%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGOBRONCHIAL FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURITIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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 EMBOLISM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 VENOUS THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	2 / 51 (3.92%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
TRACHEAL STENOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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			
ANXIETY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 MALFUNCTION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE OCCLUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
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 ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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			
CONTUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 COMPRESSION FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ACUTE CORONARY SYNDROME			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGINA PECTORIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FLUTTER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 TAMPONADE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CARDIOMYOPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALPITATIONS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 TACHYCARDIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIFASCICULAR BLOCK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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			
APHASIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL GANGLIA INFARCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CAUDA EQUINA SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSARTHRIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA HOMONYMOUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 STROKE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MIGRAINE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MONOPARESIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARTIAL SEIZURES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
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 OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIGEMINAL NEURALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 THROMBOCYTOPENIC PURPURA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
LEUKOCYTOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPH NODE PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 21 (0.00%)	2 / 51 (3.92%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 UPPER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
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 / 21 (0.00%)	3 / 51 (5.88%)	0 / 40 (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
COLITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLONIC FISTULA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (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
DIARRHOEA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (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
DUODENAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL STENOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (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
ENTEROVESICAL FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAECALOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 PERFORATION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
HAEMATEMESIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
ILEUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (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
LARGE INTESTINAL OBSTRUCTION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
PANCREATITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
SMALL INTESTINAL PERFORATION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICES OESOPHAGEAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
Hepatobiliary disorders			
AUTOIMMUNE HEPATITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 HEPATIC FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	1 / 51 (1.96%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 VEIN THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 DISEASE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
LIVER INJURY			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
Skin and subcutaneous tissue disorders			
ERYTHEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	3 / 51 (5.88%)	0 / 40 (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
AZOTAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDROURETER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 BLADDER POLYP			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTHYROIDISM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEROID WITHDRAWAL SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

ARTHRALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GROIN PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
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 PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOSITIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECK PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 IN EXTREMITY			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYMYALGIA RHEUMATICA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BARTHOLINITIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 COLITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
DIVERTICULITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KIDNEY INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECROTISING FASCIITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	2 / 51 (3.92%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 TUBERCULOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 CANDIDIASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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	1 / 21 (4.76%)	1 / 51 (1.96%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (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
HYPERLIPASAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	3 / 51 (5.88%)	0 / 40 (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
HYPOPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACTIC ACIDOSIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
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	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	117 / 201 (58.21%)	25 / 31 (80.65%)	9 / 20 (45.00%)
number of deaths (all causes)	128	23	16
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA PANCREAS			
subjects affected / exposed	0 / 201 (0.00%)	3 / 31 (9.68%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
ANAL CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 CANCER			

subjects affected / exposed	45 / 201 (22.39%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 50	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 42	0 / 0	0 / 0
BLADDER CANCER STAGE IV			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
BREAST CANCER METASTATIC			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANCER PAIN			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (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
CERVIX CARCINOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOROID MELANOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL ADENOCARCINOMA			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROOESOPHAGEAL CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GLIOBLASTOMA MULTIFORME			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRAOCULAR MELANOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 ADENOCARCINOMA			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 CANCER METASTATIC			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 NEOPLASM			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 MELANOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 NEOPLASM OF RENAL PELVIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTASES TO BLADDER			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
METASTATIC CARCINOMA OF THE BLADDER			

subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
METASTATIC GASTRIC CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NASOPHARYNGEAL CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEOPLASM SWELLING			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 ADENOCARCINOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 CANCER METASTATIC			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 CARCINOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ONCOLOGIC COMPLICATION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 CARCINOMA			
subjects affected / exposed	0 / 201 (0.00%)	8 / 31 (25.81%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 8	0 / 0
PANCREATIC CARCINOMA METASTATIC			
subjects affected / exposed	0 / 201 (0.00%)	2 / 31 (6.45%)	0 / 20 (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
PANCREATIC CARCINOMA STAGE IV			
subjects affected / exposed	0 / 201 (0.00%)	2 / 31 (6.45%)	0 / 20 (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
PARANEOPLASTIC SYNDROME			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 CELL LUNG CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE SARCOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 OF HEAD AND NECK			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 OF LUNG			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 OF PHARYNX			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 OF THE HYPOPHARYNX			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

TRANSITIONAL CELL CANCER OF THE RENAL PELVIS AND URETER			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	8 / 201 (3.98%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA METASTATIC			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
TRANSITIONAL CELL CARCINOMA RECURRENT			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
TRIPLE NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 ASSOCIATED FEVER			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
TUMOUR FLARE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
TUMOUR PAIN			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (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

VULVAL CANCER METASTATIC			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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			
EMBOLISM			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOMA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
HYPERTENSION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
SUPERIOR VENA CAVA SYNDROME			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 OCCLUSION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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
VENOUS THROMBOSIS			

subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (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
CHEST PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHILLS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (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
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	7 / 201 (3.48%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 0

MALAISE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 201 (0.50%)	1 / 31 (3.23%)	0 / 20 (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
PAIN			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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
PYREXIA			
subjects affected / exposed	3 / 201 (1.49%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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

VAGINAL DISCHARGE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
BRONCHIAL OBSTRUCTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
HAEMOPTYSIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGOBRONCHIAL FISTULA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	2 / 201 (1.00%)	1 / 31 (3.23%)	0 / 20 (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
PLEURITIC PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
PNEUMOTHORAX			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	0 / 20 (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
PULMONARY HAEMORRHAGE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 VENOUS THROMBOSIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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 DISTRESS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 FAILURE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRACHEAL STENOSIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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			
ANXIETY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			

subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
DEVICE MALFUNCTION			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
DEVICE OCCLUSION			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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

BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (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
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
TRANSAMINASES INCREASED			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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			
CONTUSION			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
FALL			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
FRACTURE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
POST PROCEDURAL COMPLICATION			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 COMPRESSION FRACTURE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
SPINAL FRACTURE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGINA PECTORIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
ATRIAL FLUTTER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 TAMPONADE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
CARDIOVASCULAR DISORDER			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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 CARDIOMYOPATHY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDITIS			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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
PALPITATIONS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 TACHYCARDIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIFASCICULAR BLOCK			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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			
APHASIA			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL GANGLIA INFARCTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CAUDA EQUINA SYNDROME			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSARTHRIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA HOMONYMOUS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 NEUROPATHY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 STROKE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MIGRAINE			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MONOPARESIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
NERVE COMPRESSION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	3 / 20 (15.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARAESTHESIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
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	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
SPINAL CORD OEDEMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIGEMINAL NEURALGIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	3 / 201 (1.49%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
IMMUNE THROMBOCYTOPENIC PURPURA			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPH NODE PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOSIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 PAIN			
subjects affected / exposed	5 / 201 (2.49%)	3 / 31 (9.68%)	0 / 20 (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
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 UPPER			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLONIC FISTULA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
CONSTIPATION			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	0 / 20 (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
DIARRHOEA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL OBSTRUCTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL STENOSIS			

subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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
DYSPHAGIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENTEROVESICAL FISTULA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
FAECALOMA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
GASTRIC PERFORATION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (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
HAEMATEMESIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 PERFORATION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
NAUSEA			
subjects affected / exposed	3 / 201 (1.49%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 4	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTITIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (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
SMALL INTESTINAL PERFORATION			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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
SUBILEUS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VARICES OESOPHAGEAL			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	5 / 201 (2.49%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 6	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
AUTOIMMUNE HEPATITIS			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 HEPATIC FAILURE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
HEPATIC FAILURE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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 FUNCTION ABNORMAL			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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 HAEMORRHAGE			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 VEIN THROMBOSIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 DISEASE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	1 / 201 (0.50%)	1 / 31 (3.23%)	0 / 20 (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
LIVER INJURY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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			
ERYTHEMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	8 / 201 (3.98%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	1 / 9	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
AZOTAEMIA			

subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (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
HYDRONEPHROSIS			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (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
HYDROURETER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 BLADDER POLYP			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (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
URINARY TRACT PAIN			

subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTHYROIDISM			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEROID WITHDRAWAL SYNDROME			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
BACK PAIN			
subjects affected / exposed	9 / 201 (4.48%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (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

GROIN PAIN			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 PAIN			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
MYOSITIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
NECK PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 IN EXTREMITY			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (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
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYMYALGIA RHEUMATICA			

subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
Infections and infestations			
ABDOMINAL ABSCESS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BARTHOLINITIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 COLITIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (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
DIVERTICULITIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED FISTULA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KIDNEY INFECTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECROTISING FASCIITIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (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
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
PULMONARY TUBERCULOSIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
PYELONEPHRITIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	8 / 201 (3.98%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMA SITE INFECTION			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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 CANDIDIASIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	9 / 201 (4.48%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 13	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			

subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	3 / 201 (1.49%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAILURE TO THRIVE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
HYPERCALCAEMIA			
subjects affected / exposed	5 / 201 (2.49%)	0 / 31 (0.00%)	0 / 20 (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
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
HYPERLIPASAEMIA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
HYPOKALAEMIA			

subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (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
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (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
HYPOPHAGIA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
LACTIC ACIDOSIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
METABOLIC ACIDOSIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (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
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
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	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 20 (35.00%)	26 / 47 (55.32%)	31 / 62 (50.00%)
number of deaths (all causes)	16	36	35
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA PANCREAS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CANCER STAGE IV			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER METASTATIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANCER PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CERVIX CARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOROID MELANOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
COLORECTAL ADENOCARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLORECTAL CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	5 / 62 (8.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 5
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
GASTRIC CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROOESOPHAGEAL CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GLIOBLASTOMA MULTIFORME			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRAOCULAR MELANOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 ADENOCARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CANCER METASTATIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 NEOPLASM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 MELANOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 NEOPLASM OF RENAL PELVIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 PLEURAL EFFUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTASES TO BLADDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC CARCINOMA OF THE BLADDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC GASTRIC CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NASOPHARYNGEAL CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEOPLASM SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-SMALL CELL LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 ADENOCARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CANCER METASTATIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ONCOLOGIC COMPLICATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CANCER			
subjects affected / exposed	0 / 20 (0.00%)	7 / 47 (14.89%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 5	0 / 0
PANCREATIC CARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CARCINOMA METASTATIC			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CARCINOMA STAGE IV			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PARANEOPLASTIC SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
PROSTATE CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SMALL CELL LUNG CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE SARCOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 OF HEAD AND NECK			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 OF LUNG			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 OF PHARYNX			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 OF THE HYPOPHARYNX			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CANCER OF THE RENAL PELVIS AND URETER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA METASTATIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSITIONAL CELL CARCINOMA RECURRENT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIPLE NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 ASSOCIATED FEVER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 FLARE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VULVAL CANCER METASTATIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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			
EMBOLISM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPERIOR VENA CAVA SYNDROME			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 OCCLUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENOUS THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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			
ASTHENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHILLS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	3 / 62 (4.84%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
MALAISE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (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
PAIN			

subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (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
PYREXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	3 / 62 (4.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL DISCHARGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
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 RESPIRATORY FAILURE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
BRONCHIAL OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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	3 / 20 (15.00%)	0 / 47 (0.00%)	3 / 62 (4.84%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGOBRONCHIAL FISTULA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURITIC PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	2 / 47 (4.26%)	0 / 62 (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 HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 VENOUS THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 FAILURE			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (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
TRACHEAL STENOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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			
ANXIETY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 MALFUNCTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE OCCLUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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			
CONTUSION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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			
ACUTE CORONARY SYNDROME			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGINA PECTORIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
ATRIAL FLUTTER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 TAMPONADE			

subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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 ARREST			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CARDIOMYOPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALPITATIONS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
SINUS TACHYCARDIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (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
TRIFASCICULAR BLOCK			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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			
APHASIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATAXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL GANGLIA INFARCTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
CAUDA EQUINA SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSARTHRIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIANOPIA HOMONYMOUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIPARESIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 NEUROPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 STROKE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MIGRAINE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MONOPARESIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVE COMPRESSION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
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 OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRIGEMINAL NEURALGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (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
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 THROMBOCYTOPENIC PURPURA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEUKOCYTOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPH NODE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 20 (0.00%)	3 / 47 (6.38%)	3 / 62 (4.84%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
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 UPPER			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
ASCITES			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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	0 / 20 (0.00%)	2 / 47 (4.26%)	0 / 62 (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
COLITIS ISCHAEMIC			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLONIC FISTULA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DUODENAL STENOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
ENTEROVESICAL FISTULA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (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
FAECALOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 PERFORATION			

subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
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 ISCHAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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 PERFORATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			

subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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 GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
RETROPERITONEAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL PERFORATION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
VARICES OESOPHAGEAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
Hepatobiliary disorders			
AUTOIMMUNE HEPATITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			

subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (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 HEPATIC FAILURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
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 HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 VEIN THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERBILIRUBINAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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			
ERYTHEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (5.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
AZOTAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDROURETER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC OBSTRUCTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY BLADDER POLYP			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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 TRACT PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTHYROIDISM			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
STEROID WITHDRAWAL SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

ARTHRALGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLANK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GROIN PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CHEST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOSITIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYMYALGIA RHEUMATICA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
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 INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BARTHOLINITIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
DIVERTICULITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED FISTULA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KIDNEY INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NECROTISING FASCIITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (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 WOUND INFECTION			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 TUBERCULOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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	1 / 20 (5.00%)	2 / 47 (4.26%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STOMA SITE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 CANDIDIASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	2 / 47 (4.26%)	2 / 62 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAILURE TO THRIVE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (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
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERLIPASAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	2 / 20 (10.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOPHAGIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACTIC ACIDOSIS			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
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 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Serious adverse events	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)	
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 21 (66.67%)	7 / 10 (70.00%)	
number of deaths (all causes)	17	7	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOCARCINOMA OF THE CERVIX			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOCARCINOMA PANCREAS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER CANCER			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER CANCER STAGE IV			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREAST CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CANCER PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CERVIX CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOROID MELANOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLON CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLORECTAL ADENOCARCINOMA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLORECTAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOMETRIAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROOESOPHAGEAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GLIOBLASTOMA MULTIFORME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATOCELLULAR CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTRAOCULAR MELANOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG ADENOCARCINOMA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG NEOPLASM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG NEOPLASM MALIGNANT			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
MALIGNANT MELANOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT NEOPLASM OF RENAL PELVIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTASES TO BLADDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTATIC CARCINOMA OF THE BLADDER			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTATIC GASTRIC CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NASOPHARYNGEAL CANCER			
subjects affected / exposed	0 / 21 (0.00%)	4 / 10 (40.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 4	
NEOPLASM SWELLING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-SMALL CELL LUNG CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-SMALL CELL LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OESOPHAGEAL ADENOCARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OESOPHAGEAL CANCER METASTATIC			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OESOPHAGEAL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ONCOLOGIC COMPLICATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OVARIAN CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATIC CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATIC CARCINOMA METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATIC CARCINOMA STAGE IV			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARANEOPLASTIC SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROSTATE CANCER			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL CELL LUNG CANCER			
subjects affected / exposed	8 / 21 (38.10%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 13	0 / 0	
deaths causally related to treatment / all	0 / 8	0 / 0	
SOFT TISSUE SARCOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA OF HEAD AND NECK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA OF LUNG			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA OF PHARYNX			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA OF THE HYPOPHARYNX			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

TRANSITIONAL CELL CANCER OF THE RENAL PELVIS AND URETER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSITIONAL CELL CARCINOMA METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSITIONAL CELL CARCINOMA RECURRENT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRIPLE NEGATIVE BREAST CANCER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUMOUR ASSOCIATED FEVER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUMOUR FLARE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUMOUR PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

VULVAL CANCER METASTATIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
EMBOLISM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTENSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTENSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUPERIOR VENA CAVA SYNDROME			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR OCCLUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENA CAVA THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENOUS THROMBOSIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHILLS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEATH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FATIGUE			
subjects affected / exposed	2 / 21 (9.52%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

MALAISE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTIPLE ORGAN DYSFUNCTION SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYREXIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

VAGINAL DISCHARGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHIAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COUGH			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA			
subjects affected / exposed	4 / 21 (19.05%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOPTYSIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

HYPOXIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OBSTRUCTIVE AIRWAYS DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OESOPHAGOBRONCHIAL FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PHARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
subjects affected / exposed	2 / 21 (9.52%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURITIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA ASPIRATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOTHORAX			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY VENOUS THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRACHEAL STENOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONFUSIONAL STATE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENTAL STATUS CHANGES			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE MALFUNCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE OCCLUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EASTERN COOPERATIVE ONCOLOGY GROUP PERFORMANCE STATUS WORSENED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSAMINASES INCREASED			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FALL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMORAL NECK FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMUR FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIP FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL COMPLICATION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANGINA PECTORIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FLUTTER			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIOVENTRICULAR BLOCK FIRST DEGREE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ARREST			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC TAMPONADE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIOVASCULAR DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ISCHAEMIC CARDIOMYOPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL INFARCTION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PALPITATIONS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERICARDIAL EFFUSION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRIFASCICULAR BLOCK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
APHASIA			

subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATAXIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BASAL GANGLIA INFARCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAUDA EQUINA SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COGNITIVE DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIZZINESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSARTHRIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FACIAL PARALYSIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEADACHE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEMIANOPIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEMIANOPIA HOMONYMOUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEMIPARESIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDROCEPHALUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ISCHAEMIC NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ISCHAEMIC STROKE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MIGRAINE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MONOPARESIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NERVE COMPRESSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARAESTHESIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARTIAL SEIZURES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEIZURE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL CORD COMPRESSION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL CORD OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYNCOPE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRIGEMINAL NEURALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DISSEMINATED INTRAVASCULAR COAGULATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMMUNE THROMBOCYTOPENIC PURPURA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LEUKOCYTOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPH NODE PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUTROPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL PAIN UPPER			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASCITES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLITIS ISCHAEMIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLONIC FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONSTIPATION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIARRHOEA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DUODENAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DUODENAL STENOSIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROVESICAL FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FAECALOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC PERFORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATEMESIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ILEUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL ISCHAEMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL PERFORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTRA-ABDOMINAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCTALGIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCTITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RETROPERITONEAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL PERFORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBILEUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VARICES OESOPHAGEAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
AUTOIMMUNE HEPATITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLANGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLECYSTITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLELITHIASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC HEPATIC FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC FAILURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC FUNCTION ABNORMAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC HAEMORRHAGE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC VEIN THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATOBILIARY DISEASE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATOCELLULAR INJURY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIVER INJURY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
ERYTHEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
AZOTAEMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDRONEPHROSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDROURETER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROTEINURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY BLADDER POLYP			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT PAIN			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
ADRENAL INSUFFICIENCY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTHYROIDISM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STEROID WITHDRAWAL SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACK PAIN			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BONE PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLANK PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

GROIN PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOSITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NECK PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POLYMYALGIA RHEUMATICA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
ABDOMINAL ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BARTHOLINITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLOSTRIDIUM DIFFICILE INFECTION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ERYSIPELAS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERPES ZOSTER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFECTED FISTULA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
KIDNEY INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NECROTISING FASCIITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEOMYELITIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERITONITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			
subjects affected / exposed	2 / 21 (9.52%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY TUBERCULOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYELONEPHRITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPTIC SHOCK			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SINUSITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STOMA SITE INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT CANDIDIASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UROSEPSIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEHYDRATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FAILURE TO THRIVE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERCALCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERKALAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERLIPASAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOKALAEMIA			

subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPONATRAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LACTIC ACIDOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METABOLIC ACIDOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUMOUR LYSIS SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Escalation Cohort (MEDI4736 0.1 mg/kg Q2W)	Escalation Cohort (MEDI4736 0.3 mg/kg Q2W)	Escalation Cohort (MEDI4736 3 mg/kg Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	4 / 4 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PERITUMOURAL OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	3
HYPOTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
CHEST DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
EARLY SATIETY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
FATIGUE			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
GAIT DISTURBANCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HERNIA PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

MALAISE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SWELLING			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
PYREXIA			
subjects affected / exposed	0 / 4 (0.00%)	3 / 4 (75.00%)	1 / 3 (33.33%)
occurrences (all)	0	3	1
SWELLING FACE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TEMPERATURE INTOLERANCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
THIRST			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

BREAST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BREAST TENDERNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
ATELECTASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
DYSPHONIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
DYSPNOEA			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
EPISTAXIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
HICCUPS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PNEUMOTHORAX			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
SNEEZING			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
AGITATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
DELIRIUM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
IRRITABILITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
LIBIDO DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RESTLESSNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CORTISOL DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
POST-TRAUMATIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SCAR			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
SKIN ABRASION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SOFT TISSUE INJURY			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
SPINAL COLUMN INJURY			

subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
EXTRASYSTOLES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
AMNESIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
APHASIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ATAXIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
BRAIN OEDEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
DIZZINESS POSTURAL			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
EXTRAPYRAMIDAL DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
HEMIPARESIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
LETHARGY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PAROSMIA			

subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
TREMOR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
VISUAL FIELD DEFECT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

SPLENOMEGALY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
EUSTACHIAN TUBE DYSFUNCTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
OTORRHOEA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVAL HYPERAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DIPLOPIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
REFRACTION DISORDER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ANAL INCONTINENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

DIARRHOEA			
subjects affected / exposed	2 / 4 (50.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
DRY MOUTH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
FAECALOMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
IMPAIRED GASTRIC EMPTYING			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
LOOSE TOOTH			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NAUSEA			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
ORAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HEPATIC PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HEPATOMEGALY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
JAUNDICE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
OCULAR ICTERUS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACNE			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
EXFOLIATIVE RASH			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PEMPHIGOID			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PRURITUS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
VITILIGO			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
AUTOIMMUNE NEPHRITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NOCTURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
POLYURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

PROTEINURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOTHYROIDISM			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
BACK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COCCYDYNIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
FOOT DEFORMITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
NECK PAIN			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PAIN IN JAW			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SYNOVIAL CYST			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ACUTE SINUSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

BRONCHITIS			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
EYE INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
OTITIS EXTERNA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PYURIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
DEHYDRATION			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
FLUID INTAKE REDUCED			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
IRON DEFICIENCY			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
POLYDIPSIA			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Escalation Cohort (MEDI4736 1 mg/kg Q2W)	Escalation Cohort (MEDI4736 15 mg/kg Q3W)	Escalation Cohort (MEDI4736 10 mg/kg Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	7 / 7 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PERITUMOURAL OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HOT FLUSH			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
HYPERTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LYMPHOEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	1 / 6 (16.67%)
occurrences (all)	0	3	1
CHEST DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
EARLY SATIETY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FATIGUE			

subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	3 / 6 (50.00%)
occurrences (all)	1	5	7
GAIT DISTURBANCE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HERNIA PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
MALAISE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

PYREXIA			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
SWELLING FACE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TEMPERATURE INTOLERANCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
THIRST			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
BREAST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BREAST TENDERNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
ATELECTASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	0 / 3 (0.00%)	4 / 7 (57.14%)	1 / 6 (16.67%)
occurrences (all)	0	7	1
DYSPHONIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

DYSPNOEA			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	1 / 6 (16.67%)
occurrences (all)	0	4	1
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
EPISTAXIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HICCUPS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PNEUMOTHORAX			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

PRODUCTIVE COUGH			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
SINUS CONGESTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SNEEZING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
WHEEZING			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
AGITATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DELIRIUM			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
INSOMNIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
IRRITABILITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LIBIDO DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RESTLESSNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1

BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CORTISOL DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
WEIGHT INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
POST-TRAUMATIC PAIN			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SCAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SOFT TISSUE INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SPINAL COLUMN INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
EXTRASYSTOLES			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PALPITATIONS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
AMNESIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
APHASIA			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
ATAXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BRAIN OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	2 / 3 (66.67%)	2 / 7 (28.57%)	0 / 6 (0.00%)
occurrences (all)	4	2	0
DIZZINESS POSTURAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
DYSGEUSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
EXTRAPYRAMIDAL DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	2	3	0
HEMIPARESIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LETHARGY			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PARAESTHESIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
PAROSMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
SYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VISUAL FIELD DEFECT			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SPLENOMEGALY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
EUSTACHIAN TUBE DYSFUNCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
OTORRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TINNITUS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVAL HYPERAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
DIPLOPIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
REFRACTION DISORDER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			

subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	0 / 6 (0.00%)
occurrences (all)	1	3	0
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
ANAL INCONTINENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	3 / 6 (50.00%)
occurrences (all)	2	1	3
DIARRHOEA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
DRY MOUTH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
DYSPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ERUCTATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FAECALOMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
IMPAIRED GASTRIC EMPTYING			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
LOOSE TOOTH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	2 / 3 (66.67%)	3 / 7 (42.86%)	1 / 6 (16.67%)
occurrences (all)	6	3	1
ORAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
VOMITING			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	1 / 6 (16.67%)
occurrences (all)	0	3	1
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HEPATIC PAIN			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HEPATOMEGALY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
JAUNDICE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
OCULAR ICTERUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

HYPERHIDROSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PEMPHIGOID			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
PETECHIAE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
PSORIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	3	1	1
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VITILIGO			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
AUTOIMMUNE NEPHRITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
NOCTURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
POLYURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOTHYROIDISM			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			

ARTHRALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
COCCYDYNIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FOOT DEFORMITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	1 / 6 (16.67%)
occurrences (all)	0	3	1

MYALGIA			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
NECK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
PAIN IN JAW			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SYNOVIAL CYST			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ACUTE SINUSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
BRONCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
EYE INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
OTITIS EXTERNA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
PYURIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	5	1	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	2 / 6 (33.33%)
occurrences (all)	1	1	3
DEHYDRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
FLUID INTAKE REDUCED			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
FLUID RETENTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
IRON DEFICIENCY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
POLYDIPSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Exploration Cohort (MEDI4736 20 mg/kg Q4W)	Expansion SCCHN Cohort (MEDI4736 10 mg/kg Q2W)	Expansion Non-SCCHN Cohort HPV+ (MEDI4736 10 mg/kg Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 21 (95.24%)	61 / 62 (98.39%)	22 / 22 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PERITUMOURAL OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
HOT FLUSH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOTENSION			
subjects affected / exposed	1 / 21 (4.76%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
LYMPHOEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

ASTHENIA			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	2 / 22 (9.09%)
occurrences (all)	0	2	4
CHEST DISCOMFORT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	2 / 21 (9.52%)	3 / 62 (4.84%)	2 / 22 (9.09%)
occurrences (all)	2	4	2
EARLY SATIETY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
FACE OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
FATIGUE			
subjects affected / exposed	8 / 21 (38.10%)	21 / 62 (33.87%)	11 / 22 (50.00%)
occurrences (all)	13	29	13
GAIT DISTURBANCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HERNIA PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	1 / 21 (4.76%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
OEDEMA PERIPHERAL			
subjects affected / exposed	4 / 21 (19.05%)	5 / 62 (8.06%)	1 / 22 (4.55%)
occurrences (all)	5	6	4
PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
PYREXIA			
subjects affected / exposed	1 / 21 (4.76%)	9 / 62 (14.52%)	4 / 22 (18.18%)
occurrences (all)	1	17	6
SWELLING FACE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
TEMPERATURE INTOLERANCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
THIRST			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
BREAST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
BREAST TENDERNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
ATELECTASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	2 / 21 (9.52%)	9 / 62 (14.52%)	2 / 22 (9.09%)
occurrences (all)	2	11	2
DYSPHONIA			
subjects affected / exposed	2 / 21 (9.52%)	2 / 62 (3.23%)	2 / 22 (9.09%)
occurrences (all)	2	2	2
DYSPNOEA			
subjects affected / exposed	2 / 21 (9.52%)	15 / 62 (24.19%)	5 / 22 (22.73%)
occurrences (all)	2	21	5
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
EPISTAXIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	1 / 21 (4.76%)	4 / 62 (6.45%)	0 / 22 (0.00%)
occurrences (all)	1	4	0
HICCUPS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
HYPOXIA			

subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
NASAL CONGESTION			
subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	1 / 22 (4.55%)
occurrences (all)	0	3	1
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	7 / 62 (11.29%)	0 / 22 (0.00%)
occurrences (all)	0	8	0
PLEURAL EFFUSION			
subjects affected / exposed	1 / 21 (4.76%)	5 / 62 (8.06%)	1 / 22 (4.55%)
occurrences (all)	1	5	2
PLEURITIC PAIN			
subjects affected / exposed	1 / 21 (4.76%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences (all)	1	2	0
PNEUMONITIS			
subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
PNEUMOTHORAX			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
PRODUCTIVE COUGH			
subjects affected / exposed	1 / 21 (4.76%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences (all)	1	2	0
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SINUS CONGESTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SNEEZING			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
Psychiatric disorders			
AGITATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
CONFUSIONAL STATE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
DELIRIUM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	1 / 21 (4.76%)	3 / 62 (4.84%)	1 / 22 (4.55%)
occurrences (all)	1	3	1
INSOMNIA			
subjects affected / exposed	1 / 21 (4.76%)	3 / 62 (4.84%)	2 / 22 (9.09%)
occurrences (all)	1	4	3
IRRITABILITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LIBIDO DECREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
RESTLESSNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	1 / 22 (4.55%)
occurrences (all)	0	1	2
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 21 (9.52%)	3 / 62 (4.84%)	2 / 22 (9.09%)
occurrences (all)	2	3	3
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 21 (9.52%)	4 / 62 (6.45%)	3 / 22 (13.64%)
occurrences (all)	2	4	3
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	4 / 62 (6.45%)	1 / 22 (4.55%)
occurrences (all)	1	4	1
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	2 / 62 (3.23%)	2 / 22 (9.09%)
occurrences (all)	1	2	3
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			

subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CORTISOL DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	2 / 21 (9.52%)	5 / 62 (8.06%)	1 / 22 (4.55%)
occurrences (all)	2	8	1
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
VITAMIN D DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	2 / 21 (9.52%)	6 / 62 (9.68%)	2 / 22 (9.09%)
occurrences (all)	2	6	3
WEIGHT INCREASED			

subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
FALL			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
POST-TRAUMATIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
SCAR			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
SOFT TISSUE INJURY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SPINAL COLUMN INJURY			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	3
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
EXTRASYSTOLES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
AMNESIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
APHASIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
ATAXIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BRAIN OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	1 / 21 (4.76%)	5 / 62 (8.06%)	0 / 22 (0.00%)
occurrences (all)	1	7	0
DIZZINESS POSTURAL			

subjects affected / exposed	2 / 21 (9.52%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
DYSARTHRIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
DYSGEUSIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
EXTRAPYRAMIDAL DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	0 / 21 (0.00%)	8 / 62 (12.90%)	2 / 22 (9.09%)
occurrences (all)	0	8	3
HEMIPARESIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
LETHARGY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 21 (4.76%)	3 / 62 (4.84%)	0 / 22 (0.00%)
occurrences (all)	1	3	0
PARAESTHESIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	2
PAROSMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
SYNCOPE			
subjects affected / exposed	0 / 21 (0.00%)	4 / 62 (6.45%)	0 / 22 (0.00%)
occurrences (all)	0	4	0
TASTE DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VISUAL FIELD DEFECT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	10 / 62 (16.13%)	5 / 22 (22.73%)
occurrences (all)	0	11	7
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

SPLENOMEGALY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
EUSTACHIAN TUBE DYSFUNCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OTORRHOEA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
TINNITUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVAL HYPERAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DIPLOPIA			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
DRY EYE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
EYE PAIN			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
REFRACTION DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	1 / 21 (4.76%)	3 / 62 (4.84%)	2 / 22 (9.09%)
occurrences (all)	1	3	2
VITREOUS FLOATERS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	2 / 21 (9.52%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	2	2	1
ABDOMINAL PAIN			
subjects affected / exposed	3 / 21 (14.29%)	5 / 62 (8.06%)	4 / 22 (18.18%)
occurrences (all)	3	6	5
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 21 (4.76%)	2 / 62 (3.23%)	3 / 22 (13.64%)
occurrences (all)	1	2	4
ANAL INCONTINENCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
CONSTIPATION			
subjects affected / exposed	2 / 21 (9.52%)	10 / 62 (16.13%)	6 / 22 (27.27%)
occurrences (all)	2	11	7

DIARRHOEA			
subjects affected / exposed	1 / 21 (4.76%)	11 / 62 (17.74%)	6 / 22 (27.27%)
occurrences (all)	1	18	9
DRY MOUTH			
subjects affected / exposed	1 / 21 (4.76%)	4 / 62 (6.45%)	0 / 22 (0.00%)
occurrences (all)	1	4	0
DYSPEPSIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
DYSPHAGIA			
subjects affected / exposed	1 / 21 (4.76%)	5 / 62 (8.06%)	0 / 22 (0.00%)
occurrences (all)	1	6	0
ERUCTATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FAECALOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
IMPAIRED GASTRIC EMPTYING			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
LOOSE TOOTH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NAUSEA			

subjects affected / exposed	2 / 21 (9.52%)	12 / 62 (19.35%)	7 / 22 (31.82%)
occurrences (all)	2	15	8
ORAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
STOMATITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
TOOTHACHE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
VOMITING			
subjects affected / exposed	1 / 21 (4.76%)	10 / 62 (16.13%)	6 / 22 (27.27%)
occurrences (all)	1	13	10
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HEPATIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HEPATOMEGALY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
JAUNDICE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OCULAR ICTERUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACNE			

subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	2 / 21 (9.52%)	3 / 62 (4.84%)	1 / 22 (4.55%)
occurrences (all)	2	3	1
ECZEMA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
ERYTHEMA			
subjects affected / exposed	0 / 21 (0.00%)	6 / 62 (9.68%)	0 / 22 (0.00%)
occurrences (all)	0	7	0
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	1 / 21 (4.76%)	1 / 62 (1.61%)	1 / 22 (4.55%)
occurrences (all)	1	1	2
NIGHT SWEATS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PEMPHIGOID			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PRURITUS			

subjects affected / exposed	3 / 21 (14.29%)	5 / 62 (8.06%)	2 / 22 (9.09%)
occurrences (all)	4	5	3
PSORIASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	1 / 21 (4.76%)	6 / 62 (9.68%)	2 / 22 (9.09%)
occurrences (all)	1	6	2
RASH MACULO-PAPULAR			
subjects affected / exposed	1 / 21 (4.76%)	4 / 62 (6.45%)	1 / 22 (4.55%)
occurrences (all)	1	6	1
VITILIGO			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
AUTOIMMUNE NEPHRITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
HAEMATURIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	1 / 22 (4.55%)
occurrences (all)	0	1	2
NOCTURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
POLYURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

PROTEINURIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
URINARY TRACT PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
HYPOTHYROIDISM			
subjects affected / exposed	3 / 21 (14.29%)	5 / 62 (8.06%)	3 / 22 (13.64%)
occurrences (all)	3	5	3
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	2 / 21 (9.52%)	4 / 62 (6.45%)	3 / 22 (13.64%)
occurrences (all)	3	9	3
BACK PAIN			
subjects affected / exposed	1 / 21 (4.76%)	7 / 62 (11.29%)	4 / 22 (18.18%)
occurrences (all)	1	7	4
COCCYDYNIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	1 / 21 (4.76%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	1	2	1
FOOT DEFORMITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	3 / 22 (13.64%)
occurrences (all)	0	3	6
JOINT SWELLING			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	2 / 21 (9.52%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	3	1	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 21 (4.76%)	5 / 62 (8.06%)	1 / 22 (4.55%)
occurrences (all)	1	5	1
MUSCULOSKELETAL PAIN			
subjects affected / exposed	3 / 21 (14.29%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	3	2	2
MYALGIA			
subjects affected / exposed	2 / 21 (9.52%)	7 / 62 (11.29%)	1 / 22 (4.55%)
occurrences (all)	3	8	1
NECK PAIN			
subjects affected / exposed	1 / 21 (4.76%)	7 / 62 (11.29%)	0 / 22 (0.00%)
occurrences (all)	1	8	0
PAIN IN EXTREMITY			
subjects affected / exposed	2 / 21 (9.52%)	1 / 62 (1.61%)	1 / 22 (4.55%)
occurrences (all)	2	1	1
PAIN IN JAW			
subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	0 / 22 (0.00%)
occurrences (all)	0	4	0
SYNOVIAL CYST			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ACUTE SINUSITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

BRONCHITIS			
subjects affected / exposed	2 / 21 (9.52%)	2 / 62 (3.23%)	2 / 22 (9.09%)
occurrences (all)	2	2	2
CANDIDA INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
EYE INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
INFLUENZA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	0 / 22 (0.00%)
occurrences (all)	0	5	0
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			

subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	2 / 22 (9.09%)
occurrences (all)	0	3	2
OTITIS EXTERNA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	1 / 22 (4.55%)
occurrences (all)	0	3	1
PYURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
RHINITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
SINUSITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SKIN INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	0 / 22 (0.00%)
occurrences (all)	0	8	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 21 (4.76%)	2 / 62 (3.23%)	5 / 22 (22.73%)
occurrences (all)	1	2	8

VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	7 / 21 (33.33%)	7 / 62 (11.29%)	4 / 22 (18.18%)
occurrences (all)	9	7	7
DEHYDRATION			
subjects affected / exposed	3 / 21 (14.29%)	7 / 62 (11.29%)	2 / 22 (9.09%)
occurrences (all)	3	8	2
FLUID INTAKE REDUCED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	7 / 62 (11.29%)	0 / 22 (0.00%)
occurrences (all)	0	7	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	0	6	3
HYPERKALAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
HYPERURICAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	3 / 62 (4.84%)	1 / 22 (4.55%)
occurrences (all)	0	4	1
HYPOCALCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
HYPOGLYCAEMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	2 / 62 (3.23%)	1 / 22 (4.55%)
occurrences (all)	0	2	1
HYPOMAGNESAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	3 / 62 (4.84%)	1 / 22 (4.55%)
occurrences (all)	1	4	1
HYPONATRAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	5 / 62 (8.06%)	1 / 22 (4.55%)
occurrences (all)	1	6	1
IRON DEFICIENCY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
POLYDIPSIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 62 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Expansion NSCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion HCC Total Cohort (MEDI4736 10 mg/kg Q2W)	Expansion UM Cohort (MEDI4736 10 mg/kg Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	293 / 304 (96.38%)	40 / 40 (100.00%)	22 / 24 (91.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
PERITUMOURAL OEDEMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
Vascular disorders			

DEEP VEIN THROMBOSIS			
subjects affected / exposed	3 / 304 (0.99%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	3	1	0
HOT FLUSH			
subjects affected / exposed	4 / 304 (1.32%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	4	2	0
HYPERTENSION			
subjects affected / exposed	11 / 304 (3.62%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	16	1	0
HYPOTENSION			
subjects affected / exposed	12 / 304 (3.95%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	12	1	0
LYMPHOEDEMA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	14 / 304 (4.61%)	6 / 40 (15.00%)	5 / 24 (20.83%)
occurrences (all)	16	12	6
CHEST DISCOMFORT			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
CHEST PAIN			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
CHILLS			
subjects affected / exposed	13 / 304 (4.28%)	3 / 40 (7.50%)	1 / 24 (4.17%)
occurrences (all)	13	3	1
EARLY SATIETY			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
FACE OEDEMA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
FATIGUE			

subjects affected / exposed	114 / 304 (37.50%)	20 / 40 (50.00%)	9 / 24 (37.50%)
occurrences (all)	165	23	12
GAIT DISTURBANCE			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	1 / 304 (0.33%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	1	3	0
GENERALISED OEDEMA			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
HERNIA PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	7 / 304 (2.30%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	7	2	0
MALAISE			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	4 / 304 (1.32%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences (all)	4	1	1
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	17 / 304 (5.59%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	18	1	0
OEDEMA PERIPHERAL			
subjects affected / exposed	31 / 304 (10.20%)	11 / 40 (27.50%)	2 / 24 (8.33%)
occurrences (all)	42	17	3
PAIN			
subjects affected / exposed	9 / 304 (2.96%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	11	1	0
PERIPHERAL SWELLING			
subjects affected / exposed	5 / 304 (1.64%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	5	2	0

PYREXIA			
subjects affected / exposed	33 / 304 (10.86%)	6 / 40 (15.00%)	2 / 24 (8.33%)
occurrences (all)	45	18	3
SWELLING FACE			
subjects affected / exposed	1 / 304 (0.33%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
TEMPERATURE INTOLERANCE			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
THIRST			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
BREAST PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
BREAST TENDERNESS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 304 (0.00%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	0	3	0
Respiratory, thoracic and mediastinal disorders			
ATELECTASIS			
subjects affected / exposed	1 / 304 (0.33%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
COUGH			
subjects affected / exposed	77 / 304 (25.33%)	7 / 40 (17.50%)	5 / 24 (20.83%)
occurrences (all)	102	8	6
DYSPHONIA			
subjects affected / exposed	13 / 304 (4.28%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	15	0	0

DYSPNOEA			
subjects affected / exposed	75 / 304 (24.67%)	8 / 40 (20.00%)	6 / 24 (25.00%)
occurrences (all)	100	10	6
DYSPNOEA EXERTIONAL			
subjects affected / exposed	8 / 304 (2.63%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	9	1	0
EPISTAXIS			
subjects affected / exposed	8 / 304 (2.63%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	9	1	0
HAEMOPTYSIS			
subjects affected / exposed	24 / 304 (7.89%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	29	0	0
HICCUPS			
subjects affected / exposed	3 / 304 (0.99%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	4	2	0
HYPOXIA			
subjects affected / exposed	8 / 304 (2.63%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	9	0	1
NASAL CONGESTION			
subjects affected / exposed	10 / 304 (3.29%)	0 / 40 (0.00%)	3 / 24 (12.50%)
occurrences (all)	13	0	4
OROPHARYNGEAL PAIN			
subjects affected / exposed	17 / 304 (5.59%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	20	0	0
PLEURAL EFFUSION			
subjects affected / exposed	14 / 304 (4.61%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	19	2	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	6 / 304 (1.97%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	8	0	0
PNEUMOTHORAX			
subjects affected / exposed	5 / 304 (1.64%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	5	0	0

PRODUCTIVE COUGH			
subjects affected / exposed	20 / 304 (6.58%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	23	1	0
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
RHINORRHOEA			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	5	0	0
SINUS CONGESTION			
subjects affected / exposed	3 / 304 (0.99%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	3	2	0
SNEEZING			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	8 / 304 (2.63%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	8	0	0
WHEEZING			
subjects affected / exposed	15 / 304 (4.93%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	17	0	0
Psychiatric disorders			
AGITATION			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
ANXIETY			
subjects affected / exposed	16 / 304 (5.26%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences (all)	18	2	1
CONFUSIONAL STATE			
subjects affected / exposed	5 / 304 (1.64%)	2 / 40 (5.00%)	1 / 24 (4.17%)
occurrences (all)	5	2	1
DELIRIUM			

subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
DEPRESSION			
subjects affected / exposed	10 / 304 (3.29%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences (all)	10	2	1
INSOMNIA			
subjects affected / exposed	24 / 304 (7.89%)	7 / 40 (17.50%)	2 / 24 (8.33%)
occurrences (all)	26	7	6
IRRITABILITY			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	4	0	1
LIBIDO DECREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
RESTLESSNESS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	3 / 304 (0.99%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	3	1	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	19 / 304 (6.25%)	9 / 40 (22.50%)	1 / 24 (4.17%)
occurrences (all)	25	20	1
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	20 / 304 (6.58%)	20 / 40 (50.00%)	2 / 24 (8.33%)
occurrences (all)	26	30	2
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	16 / 304 (5.26%)	9 / 40 (22.50%)	4 / 24 (16.67%)
occurrences (all)	21	14	4

BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	8 / 304 (2.63%)	6 / 40 (15.00%)	3 / 24 (12.50%)
occurrences (all)	12	8	6
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	12 / 304 (3.95%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	21	2	0
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN INCREASED			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE DECREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	8 / 304 (2.63%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	10	2	0
CORTISOL DECREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	12 / 304 (3.95%)	8 / 40 (20.00%)	3 / 24 (12.50%)
occurrences (all)	13	10	5
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	3 / 304 (0.99%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	4	5	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
TRANSAMINASES INCREASED			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
VITAMIN D DECREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	24 / 304 (7.89%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	30	2	0
WEIGHT INCREASED			
subjects affected / exposed	9 / 304 (2.96%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	14	2	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	6	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
FALL			
subjects affected / exposed	7 / 304 (2.30%)	0 / 40 (0.00%)	2 / 24 (8.33%)
occurrences (all)	8	0	3
INFUSION RELATED REACTION			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
POST-TRAUMATIC PAIN			

subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	2
PROCEDURAL PAIN			
subjects affected / exposed	5 / 304 (1.64%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	5	0	0
SCAR			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	3	1	0
SOFT TISSUE INJURY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
SPINAL COLUMN INJURY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	5 / 304 (1.64%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	6	3	0
EXTRASYSTOLES			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
PALPITATIONS			
subjects affected / exposed	6 / 304 (1.97%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	7	2	0
SINUS TACHYCARDIA			
subjects affected / exposed	7 / 304 (2.30%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	7	1	0
Nervous system disorders			
AMNESIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
APHASIA			

subjects affected / exposed	1 / 304 (0.33%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
ATAXIA			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
BRAIN OEDEMA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	23 / 304 (7.57%)	6 / 40 (15.00%)	2 / 24 (8.33%)
occurrences (all)	24	6	2
DIZZINESS POSTURAL			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	5 / 304 (1.64%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	5	0	1
EXTRAPYRAMIDAL DISORDER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	33 / 304 (10.86%)	1 / 40 (2.50%)	4 / 24 (16.67%)
occurrences (all)	46	1	5
HEMIPARESIS			
subjects affected / exposed	1 / 304 (0.33%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
HYPOAESTHESIA			
subjects affected / exposed	3 / 304 (0.99%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	3	1	0
LETHARGY			

subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	7 / 304 (2.30%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	8	1	0
PARAESTHESIA			
subjects affected / exposed	6 / 304 (1.97%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	7	0	0
PAROSMIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
SOMNOLENCE			
subjects affected / exposed	1 / 304 (0.33%)	3 / 40 (7.50%)	1 / 24 (4.17%)
occurrences (all)	1	3	2
SYNCOPE			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
TASTE DISORDER			
subjects affected / exposed	4 / 304 (1.32%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
TREMOR			
subjects affected / exposed	6 / 304 (1.97%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	7	1	0
VISUAL FIELD DEFECT			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	47 / 304 (15.46%)	5 / 40 (12.50%)	1 / 24 (4.17%)
occurrences (all)	74	6	1
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
LEUKOPENIA			
subjects affected / exposed	3 / 304 (0.99%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	4	3	0
NEUTROPENIA			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	8	3	0
SPLENOMEGALY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	8 / 304 (2.63%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	12	7	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	3	1	0
EUSTACHIAN TUBE DYSFUNCTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
OTORRHOEA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
TINNITUS			

subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	1
Eye disorders			
CATARACT			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
CONJUNCTIVAL HYPERAEMIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
DIPLOPIA			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
DRY EYE			
subjects affected / exposed	6 / 304 (1.97%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences (all)	6	1	1
EYE PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
REFRACTION DISORDER			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	7 / 304 (2.30%)	2 / 40 (5.00%)	1 / 24 (4.17%)
occurrences (all)	7	2	1
VITREOUS FLOATERS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 304 (0.33%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
ABDOMINAL DISTENSION			
subjects affected / exposed	9 / 304 (2.96%)	5 / 40 (12.50%)	1 / 24 (4.17%)
occurrences (all)	10	5	1
ABDOMINAL PAIN			

subjects affected / exposed	23 / 304 (7.57%)	11 / 40 (27.50%)	4 / 24 (16.67%)
occurrences (all)	28	12	4
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 304 (0.00%)	3 / 40 (7.50%)	1 / 24 (4.17%)
occurrences (all)	0	3	1
ABDOMINAL PAIN UPPER			
subjects affected / exposed	7 / 304 (2.30%)	8 / 40 (20.00%)	4 / 24 (16.67%)
occurrences (all)	7	11	4
ANAL INCONTINENCE			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
ASCITES			
subjects affected / exposed	2 / 304 (0.66%)	4 / 40 (10.00%)	0 / 24 (0.00%)
occurrences (all)	2	6	0
CONSTIPATION			
subjects affected / exposed	48 / 304 (15.79%)	11 / 40 (27.50%)	4 / 24 (16.67%)
occurrences (all)	55	12	4
DIARRHOEA			
subjects affected / exposed	53 / 304 (17.43%)	10 / 40 (25.00%)	5 / 24 (20.83%)
occurrences (all)	96	12	10
DRY MOUTH			
subjects affected / exposed	17 / 304 (5.59%)	4 / 40 (10.00%)	1 / 24 (4.17%)
occurrences (all)	19	4	1
DYSPEPSIA			
subjects affected / exposed	10 / 304 (3.29%)	4 / 40 (10.00%)	2 / 24 (8.33%)
occurrences (all)	11	4	2
DYSPHAGIA			
subjects affected / exposed	15 / 304 (4.93%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	18	1	0
ERUCTATION			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
FAECALOMA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			

subjects affected / exposed	3 / 304 (0.99%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	3	2	0
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	11 / 304 (3.62%)	2 / 40 (5.00%)	1 / 24 (4.17%)
occurrences (all)	13	2	1
IMPAIRED GASTRIC EMPTYING			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
LOOSE TOOTH			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	67 / 304 (22.04%)	14 / 40 (35.00%)	10 / 24 (41.67%)
occurrences (all)	82	16	14
ORAL PAIN			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
STOMATITIS			
subjects affected / exposed	4 / 304 (1.32%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	5	1	0
TOOTHACHE			
subjects affected / exposed	8 / 304 (2.63%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	12	0	0
VOMITING			
subjects affected / exposed	41 / 304 (13.49%)	10 / 40 (25.00%)	4 / 24 (16.67%)
occurrences (all)	53	16	4
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
HEPATIC PAIN			

subjects affected / exposed	0 / 304 (0.00%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
HEPATOMEGALY			
subjects affected / exposed	0 / 304 (0.00%)	2 / 40 (5.00%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
HYPERBILIRUBINAEMIA			
subjects affected / exposed	1 / 304 (0.33%)	3 / 40 (7.50%)	0 / 24 (0.00%)
occurrences (all)	1	6	0
JAUNDICE			
subjects affected / exposed	2 / 304 (0.66%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	2	2	0
OCULAR ICTERUS			
subjects affected / exposed	0 / 304 (0.00%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	14 / 304 (4.61%)	0 / 40 (0.00%)	2 / 24 (8.33%)
occurrences (all)	15	0	2
ECZEMA			
subjects affected / exposed	5 / 304 (1.64%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	5	0	0
ERYTHEMA			
subjects affected / exposed	6 / 304 (1.97%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences (all)	6	1	1
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

HYPERHIDROSIS			
subjects affected / exposed	5 / 304 (1.64%)	0 / 40 (0.00%)	2 / 24 (8.33%)
occurrences (all)	5	0	2
NIGHT SWEATS			
subjects affected / exposed	8 / 304 (2.63%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	8	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
PEMPHIGOID			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
PRURITUS			
subjects affected / exposed	35 / 304 (11.51%)	16 / 40 (40.00%)	4 / 24 (16.67%)
occurrences (all)	49	20	4
PSORIASIS			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
RASH			
subjects affected / exposed	37 / 304 (12.17%)	5 / 40 (12.50%)	7 / 24 (29.17%)
occurrences (all)	54	7	12
RASH MACULO-PAPULAR			
subjects affected / exposed	7 / 304 (2.30%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences (all)	13	1	1
VITILIGO			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
AUTOIMMUNE NEPHRITIS			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
HAEMATURIA			
subjects affected / exposed	1 / 304 (0.33%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
NOCTURIA			
subjects affected / exposed	0 / 304 (0.00%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
POLLAKIURIA			
subjects affected / exposed	2 / 304 (0.66%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	2	2	0
POLYURIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	9 / 304 (2.96%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	11	3	0
URINARY INCONTINENCE			
subjects affected / exposed	3 / 304 (0.99%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	12 / 304 (3.95%)	2 / 40 (5.00%)	1 / 24 (4.17%)
occurrences (all)	19	2	1
HYPOTHYROIDISM			
subjects affected / exposed	29 / 304 (9.54%)	4 / 40 (10.00%)	1 / 24 (4.17%)
occurrences (all)	34	4	1
Musculoskeletal and connective tissue disorders			

ARTHRALGIA			
subjects affected / exposed	44 / 304 (14.47%)	6 / 40 (15.00%)	4 / 24 (16.67%)
occurrences (all)	62	6	5
BACK PAIN			
subjects affected / exposed	49 / 304 (16.12%)	6 / 40 (15.00%)	2 / 24 (8.33%)
occurrences (all)	56	6	5
COCCYDYNIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
FOOT DEFORMITY			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	1 / 304 (0.33%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
JOINT SWELLING			
subjects affected / exposed	1 / 304 (0.33%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
MUSCLE SPASMS			
subjects affected / exposed	10 / 304 (3.29%)	1 / 40 (2.50%)	4 / 24 (16.67%)
occurrences (all)	10	1	4
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	8 / 304 (2.63%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	11	1	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	25 / 304 (8.22%)	4 / 40 (10.00%)	1 / 24 (4.17%)
occurrences (all)	31	4	1
MUSCULOSKELETAL PAIN			
subjects affected / exposed	18 / 304 (5.92%)	6 / 40 (15.00%)	2 / 24 (8.33%)
occurrences (all)	23	8	2

MYALGIA			
subjects affected / exposed	31 / 304 (10.20%)	3 / 40 (7.50%)	5 / 24 (20.83%)
occurrences (all)	41	5	7
NECK PAIN			
subjects affected / exposed	7 / 304 (2.30%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	7	1	0
PAIN IN EXTREMITY			
subjects affected / exposed	26 / 304 (8.55%)	3 / 40 (7.50%)	0 / 24 (0.00%)
occurrences (all)	32	4	0
PAIN IN JAW			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
SYNOVIAL CYST			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ACUTE SINUSITIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
BRONCHITIS			
subjects affected / exposed	11 / 304 (3.62%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	12	2	0
CANDIDA INFECTION			
subjects affected / exposed	2 / 304 (0.66%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
EYE INFECTION			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
FOLLICULITIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			

subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
GINGIVITIS			
subjects affected / exposed	3 / 304 (0.99%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	3	2	0
HERPES ZOSTER			
subjects affected / exposed	6 / 304 (1.97%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	6	0	0
INFLUENZA			
subjects affected / exposed	5 / 304 (1.64%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	5	1	0
NASOPHARYNGITIS			
subjects affected / exposed	8 / 304 (2.63%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	9	1	0
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	13 / 304 (4.28%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	15	0	0
OTITIS EXTERNA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	5 / 304 (1.64%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	6	0	0
PNEUMONIA			
subjects affected / exposed	25 / 304 (8.22%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	34	2	0
PYURIA			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	6 / 304 (1.97%)	1 / 40 (2.50%)	1 / 24 (4.17%)
occurrences (all)	6	1	1
SINUSITIS			
subjects affected / exposed	12 / 304 (3.95%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	14	3	0
SKIN INFECTION			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	23 / 304 (7.57%)	1 / 40 (2.50%)	4 / 24 (16.67%)
occurrences (all)	29	1	4
URINARY TRACT INFECTION			
subjects affected / exposed	15 / 304 (4.93%)	4 / 40 (10.00%)	2 / 24 (8.33%)
occurrences (all)	17	6	2
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	80 / 304 (26.32%)	15 / 40 (37.50%)	5 / 24 (20.83%)
occurrences (all)	112	17	5
DEHYDRATION			
subjects affected / exposed	18 / 304 (5.92%)	0 / 40 (0.00%)	1 / 24 (4.17%)
occurrences (all)	24	0	1
FLUID INTAKE REDUCED			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
FLUID RETENTION			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
HYPERCALCAEMIA			

subjects affected / exposed	16 / 304 (5.26%)	3 / 40 (7.50%)	0 / 24 (0.00%)
occurrences (all)	19	4	0
HYPERGLYCAEMIA			
subjects affected / exposed	12 / 304 (3.95%)	4 / 40 (10.00%)	0 / 24 (0.00%)
occurrences (all)	15	4	0
HYPERKALAEMIA			
subjects affected / exposed	7 / 304 (2.30%)	1 / 40 (2.50%)	2 / 24 (8.33%)
occurrences (all)	7	1	2
HYPERURICAEMIA			
subjects affected / exposed	6 / 304 (1.97%)	3 / 40 (7.50%)	0 / 24 (0.00%)
occurrences (all)	6	4	0
HYPOALBUMINAEMIA			
subjects affected / exposed	20 / 304 (6.58%)	4 / 40 (10.00%)	0 / 24 (0.00%)
occurrences (all)	22	4	0
HYPOCALCAEMIA			
subjects affected / exposed	5 / 304 (1.64%)	1 / 40 (2.50%)	0 / 24 (0.00%)
occurrences (all)	6	1	0
HYPOGLYCAEMIA			
subjects affected / exposed	2 / 304 (0.66%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
HYPOKALAEMIA			
subjects affected / exposed	22 / 304 (7.24%)	2 / 40 (5.00%)	0 / 24 (0.00%)
occurrences (all)	29	4	0
HYPOMAGNESAEMIA			
subjects affected / exposed	13 / 304 (4.28%)	3 / 40 (7.50%)	1 / 24 (4.17%)
occurrences (all)	17	6	1
HYPONATRAEMIA			
subjects affected / exposed	31 / 304 (10.20%)	5 / 40 (12.50%)	1 / 24 (4.17%)
occurrences (all)	49	8	3
IRON DEFICIENCY			
subjects affected / exposed	1 / 304 (0.33%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
POLYDIPSIA			
subjects affected / exposed	0 / 304 (0.00%)	0 / 40 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Expansion ACM Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GEC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion TNBC Cohort (MEDI4736 10 mg/kg Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 21 (90.48%)	50 / 51 (98.04%)	40 / 40 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	3 / 40 (7.50%)
occurrences (all)	0	0	3
PERITUMOURAL OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	2 / 21 (9.52%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
HYPERTENSION			
subjects affected / exposed	1 / 21 (4.76%)	2 / 51 (3.92%)	1 / 40 (2.50%)
occurrences (all)	1	2	2
HYPOTENSION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
LYMPHOEDEMA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
General disorders and administration site conditions			
ASTHENIA			

subjects affected / exposed	1 / 21 (4.76%)	3 / 51 (5.88%)	5 / 40 (12.50%)
occurrences (all)	1	3	6
CHEST DISCOMFORT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	4 / 21 (19.05%)	4 / 51 (7.84%)	0 / 40 (0.00%)
occurrences (all)	4	4	0
EARLY SATIETY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
FACE OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	10 / 21 (47.62%)	28 / 51 (54.90%)	7 / 40 (17.50%)
occurrences (all)	10	73	11
GAIT DISTURBANCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
GENERALISED OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
HERNIA PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	2 / 40 (5.00%)
occurrences (all)	3	1	2

MALAISE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	1 / 21 (4.76%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	2	2	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
OEDEMA PERIPHERAL			
subjects affected / exposed	3 / 21 (14.29%)	5 / 51 (9.80%)	6 / 40 (15.00%)
occurrences (all)	3	5	8
PAIN			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
PERIPHERAL SWELLING			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
PYREXIA			
subjects affected / exposed	4 / 21 (19.05%)	7 / 51 (13.73%)	6 / 40 (15.00%)
occurrences (all)	5	14	6
SWELLING FACE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
TEMPERATURE INTOLERANCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
THIRST			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

BREAST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
BREAST TENDERNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
ATELECTASIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
COUGH			
subjects affected / exposed	4 / 21 (19.05%)	12 / 51 (23.53%)	5 / 40 (12.50%)
occurrences (all)	4	15	5
DYSPHONIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
DYSPNOEA			
subjects affected / exposed	2 / 21 (9.52%)	17 / 51 (33.33%)	10 / 40 (25.00%)
occurrences (all)	2	22	14
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
EPISTAXIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
HICCUPS			
subjects affected / exposed	0 / 21 (0.00%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	0	8	0
HYPOXIA			

subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
NASAL CONGESTION			
subjects affected / exposed	1 / 21 (4.76%)	4 / 51 (7.84%)	0 / 40 (0.00%)
occurrences (all)	1	4	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 21 (4.76%)	2 / 51 (3.92%)	1 / 40 (2.50%)
occurrences (all)	1	2	1
PLEURAL EFFUSION			
subjects affected / exposed	0 / 21 (0.00%)	2 / 51 (3.92%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
PLEURITIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
PNEUMOTHORAX			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
SINUS CONGESTION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
SNEEZING			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	2 / 21 (9.52%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	2	0	1
WHEEZING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
AGITATION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
ANXIETY			
subjects affected / exposed	1 / 21 (4.76%)	2 / 51 (3.92%)	2 / 40 (5.00%)
occurrences (all)	1	2	2
CONFUSIONAL STATE			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
DELIRIUM			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
DEPRESSION			
subjects affected / exposed	1 / 21 (4.76%)	3 / 51 (5.88%)	0 / 40 (0.00%)
occurrences (all)	1	3	0
INSOMNIA			
subjects affected / exposed	1 / 21 (4.76%)	13 / 51 (25.49%)	2 / 40 (5.00%)
occurrences (all)	4	25	2
IRRITABILITY			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
LIBIDO DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
RESTLESSNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	3	1
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	4 / 40 (10.00%)
occurrences (all)	2	1	4
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 21 (9.52%)	3 / 51 (5.88%)	7 / 40 (17.50%)
occurrences (all)	3	5	12
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	3 / 51 (5.88%)	4 / 40 (10.00%)
occurrences (all)	0	3	4
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	1	3	3
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	2 / 21 (9.52%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	5	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	1	4	0
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			

subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	2 / 40 (5.00%)
occurrences (all)	1	0	2
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
CORTISOL DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	3 / 51 (5.88%)	7 / 40 (17.50%)
occurrences (all)	0	3	11
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
VITAMIN D DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	1 / 21 (4.76%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	2	2	0
WEIGHT INCREASED			

subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	2	1	1
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
POST-TRAUMATIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
SCAR			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
SOFT TISSUE INJURY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
SPINAL COLUMN INJURY			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
EXTRASYSTOLES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
AMNESIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
APHASIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
ATAXIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
BRAIN OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	3 / 21 (14.29%)	9 / 51 (17.65%)	4 / 40 (10.00%)
occurrences (all)	4	22	5
DIZZINESS POSTURAL			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	2
DYSGEUSIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
EXTRAPYRAMIDAL DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	2 / 21 (9.52%)	5 / 51 (9.80%)	7 / 40 (17.50%)
occurrences (all)	2	6	8
HEMIPARESIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
HYPOAESTHESIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
LETHARGY			
subjects affected / exposed	2 / 21 (9.52%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	2	2	0
MEMORY IMPAIRMENT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 21 (4.76%)	4 / 51 (7.84%)	2 / 40 (5.00%)
occurrences (all)	1	5	2
PARAESTHESIA			
subjects affected / exposed	2 / 21 (9.52%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
PAROSMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	2 / 21 (9.52%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
SOMNOLENCE			
subjects affected / exposed	0 / 21 (0.00%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
SYNCOPE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
TASTE DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	0	6	0
TREMOR			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
VISUAL FIELD DEFECT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	3 / 21 (14.29%)	7 / 51 (13.73%)	2 / 40 (5.00%)
occurrences (all)	12	20	7
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1

SPLENOMEGALY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
EUSTACHIAN TUBE DYSFUNCTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
OTORRHOEA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVAL HYPERAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
DIPLOPIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
DRY EYE			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
EYE PAIN			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
REFRACTION DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	1 / 21 (4.76%)	2 / 51 (3.92%)	2 / 40 (5.00%)
occurrences (all)	1	4	2
VITREOUS FLOATERS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 21 (0.00%)	3 / 51 (5.88%)	0 / 40 (0.00%)
occurrences (all)	0	3	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 21 (4.76%)	13 / 51 (25.49%)	2 / 40 (5.00%)
occurrences (all)	2	27	4
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 21 (0.00%)	4 / 51 (7.84%)	4 / 40 (10.00%)
occurrences (all)	0	4	5
ANAL INCONTINENCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 21 (0.00%)	5 / 51 (9.80%)	1 / 40 (2.50%)
occurrences (all)	0	5	1
CONSTIPATION			
subjects affected / exposed	4 / 21 (19.05%)	16 / 51 (31.37%)	5 / 40 (12.50%)
occurrences (all)	4	20	5

DIARRHOEA			
subjects affected / exposed	5 / 21 (23.81%)	17 / 51 (33.33%)	5 / 40 (12.50%)
occurrences (all)	8	19	6
DRY MOUTH			
subjects affected / exposed	1 / 21 (4.76%)	5 / 51 (9.80%)	2 / 40 (5.00%)
occurrences (all)	2	7	2
DYSPEPSIA			
subjects affected / exposed	1 / 21 (4.76%)	3 / 51 (5.88%)	1 / 40 (2.50%)
occurrences (all)	1	3	1
DYSPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	10 / 51 (19.61%)	2 / 40 (5.00%)
occurrences (all)	0	12	6
ERUCTATION			
subjects affected / exposed	0 / 21 (0.00%)	3 / 51 (5.88%)	0 / 40 (0.00%)
occurrences (all)	0	9	0
FAECALOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 21 (0.00%)	3 / 51 (5.88%)	1 / 40 (2.50%)
occurrences (all)	0	9	1
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 21 (4.76%)	7 / 51 (13.73%)	2 / 40 (5.00%)
occurrences (all)	1	18	2
IMPAIRED GASTRIC EMPTYING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
LOOSE TOOTH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
NAUSEA			

subjects affected / exposed	5 / 21 (23.81%)	13 / 51 (25.49%)	9 / 40 (22.50%)
occurrences (all)	8	26	9
ORAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	1 / 21 (4.76%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	1	5	0
TOOTHACHE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
VOMITING			
subjects affected / exposed	5 / 21 (23.81%)	10 / 51 (19.61%)	7 / 40 (17.50%)
occurrences (all)	5	35	8
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
HEPATIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
HEPATOMEGALY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
JAUNDICE			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
OCULAR ICTERUS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
ACNE			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 21 (0.00%)	2 / 51 (3.92%)	2 / 40 (5.00%)
occurrences (all)	0	2	3
ECZEMA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
ERYTHEMA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	2 / 40 (5.00%)
occurrences (all)	0	4	2
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 21 (0.00%)	5 / 51 (9.80%)	1 / 40 (2.50%)
occurrences (all)	0	15	1
NIGHT SWEATS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
PEMPHIGOID			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
PRURITUS			

subjects affected / exposed	5 / 21 (23.81%)	6 / 51 (11.76%)	5 / 40 (12.50%)
occurrences (all)	7	8	6
PSORIASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	4 / 21 (19.05%)	9 / 51 (17.65%)	1 / 40 (2.50%)
occurrences (all)	7	13	1
RASH MACULO-PAPULAR			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
VITILIGO			
subjects affected / exposed	2 / 21 (9.52%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
AUTOIMMUNE NEPHRITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
HAEMATURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
NOCTURIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
POLLAKIURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
POLYURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

PROTEINURIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	3	0	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
HYPOTHYROIDISM			
subjects affected / exposed	3 / 21 (14.29%)	2 / 51 (3.92%)	4 / 40 (10.00%)
occurrences (all)	4	2	5
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	9 / 21 (42.86%)	1 / 51 (1.96%)	4 / 40 (10.00%)
occurrences (all)	14	2	5
BACK PAIN			
subjects affected / exposed	3 / 21 (14.29%)	13 / 51 (25.49%)	6 / 40 (15.00%)
occurrences (all)	3	16	6
COCCYDYNIA			
subjects affected / exposed	2 / 21 (9.52%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
FLANK PAIN			
subjects affected / exposed	1 / 21 (4.76%)	2 / 51 (3.92%)	1 / 40 (2.50%)
occurrences (all)	1	2	1
FOOT DEFORMITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
JOINT SWELLING			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	3 / 21 (14.29%)	1 / 51 (1.96%)	6 / 40 (15.00%)
occurrences (all)	3	1	9
MUSCULOSKELETAL PAIN			
subjects affected / exposed	2 / 21 (9.52%)	5 / 51 (9.80%)	2 / 40 (5.00%)
occurrences (all)	2	33	3
MYALGIA			
subjects affected / exposed	2 / 21 (9.52%)	3 / 51 (5.88%)	4 / 40 (10.00%)
occurrences (all)	2	3	5
NECK PAIN			
subjects affected / exposed	2 / 21 (9.52%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	2	3	0
PAIN IN EXTREMITY			
subjects affected / exposed	3 / 21 (14.29%)	2 / 51 (3.92%)	2 / 40 (5.00%)
occurrences (all)	3	2	2
PAIN IN JAW			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
SYNOVIAL CYST			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ACUTE SINUSITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

BRONCHITIS			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	2 / 40 (5.00%)
occurrences (all)	1	1	2
CANDIDA INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
EYE INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	1 / 21 (4.76%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
INFLUENZA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			

subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
OTITIS EXTERNA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
PYURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
SINUSITIS			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
SKIN INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 21 (9.52%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	2	2	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	3 / 51 (5.88%)	2 / 40 (5.00%)
occurrences (all)	0	3	2

VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	6 / 21 (28.57%)	22 / 51 (43.14%)	6 / 40 (15.00%)
occurrences (all)	6	38	6
DEHYDRATION			
subjects affected / exposed	4 / 21 (19.05%)	8 / 51 (15.69%)	2 / 40 (5.00%)
occurrences (all)	4	11	2
FLUID INTAKE REDUCED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
HYPERCALCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	2 / 51 (3.92%)	0 / 40 (0.00%)
occurrences (all)	0	7	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 51 (1.96%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	3 / 40 (7.50%)
occurrences (all)	0	0	4
HYPOCALCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	4 / 51 (7.84%)	1 / 40 (2.50%)
occurrences (all)	0	6	1
HYPOGLYCAEMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
HYPOKALAEMIA			
subjects affected / exposed	2 / 21 (9.52%)	1 / 51 (1.96%)	2 / 40 (5.00%)
occurrences (all)	3	1	2
HYPOMAGNESAEMIA			
subjects affected / exposed	2 / 21 (9.52%)	2 / 51 (3.92%)	1 / 40 (2.50%)
occurrences (all)	4	2	1
HYPONATRAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	5 / 51 (9.80%)	3 / 40 (7.50%)
occurrences (all)	0	5	5
IRON DEFICIENCY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
POLYDIPSIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 51 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Expansion UC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion PAC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion GBM Cohort (MEDI4736 10 mg/kg Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	196 / 201 (97.51%)	31 / 31 (100.00%)	18 / 20 (90.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	6	0	0
PERITUMOURAL OEDEMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
TUMOUR PAIN			
subjects affected / exposed	10 / 201 (4.98%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	12	0	0
Vascular disorders			

DEEP VEIN THROMBOSIS			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
HOT FLUSH			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
HYPERTENSION			
subjects affected / exposed	7 / 201 (3.48%)	0 / 31 (0.00%)	3 / 20 (15.00%)
occurrences (all)	13	0	3
HYPOTENSION			
subjects affected / exposed	10 / 201 (4.98%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	12	0	0
LYMPHOEDEMA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	26 / 201 (12.94%)	0 / 31 (0.00%)	2 / 20 (10.00%)
occurrences (all)	44	0	2
CHEST DISCOMFORT			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	2 / 20 (10.00%)
occurrences (all)	3	0	2
CHEST PAIN			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
CHILLS			
subjects affected / exposed	8 / 201 (3.98%)	6 / 31 (19.35%)	2 / 20 (10.00%)
occurrences (all)	10	7	2
EARLY SATIETY			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
FACE OEDEMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FATIGUE			

subjects affected / exposed	73 / 201 (36.32%)	19 / 31 (61.29%)	8 / 20 (40.00%)
occurrences (all)	91	24	8
GAIT DISTURBANCE			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	2 / 20 (10.00%)
occurrences (all)	2	0	3
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HERNIA PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
MALAISE			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	1 / 20 (5.00%)
occurrences (all)	2	1	1
MUCOSAL INFLAMMATION			
subjects affected / exposed	6 / 201 (2.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	6	0	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
OEDEMA PERIPHERAL			
subjects affected / exposed	28 / 201 (13.93%)	3 / 31 (9.68%)	1 / 20 (5.00%)
occurrences (all)	33	3	1
PAIN			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
PERIPHERAL SWELLING			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

PYREXIA			
subjects affected / exposed	28 / 201 (13.93%)	4 / 31 (12.90%)	3 / 20 (15.00%)
occurrences (all)	34	4	3
SWELLING FACE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
TEMPERATURE INTOLERANCE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
THIRST			
subjects affected / exposed	0 / 201 (0.00%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
BREAST PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BREAST TENDERNESS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PELVIC PAIN			
subjects affected / exposed	4 / 201 (1.99%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	5	1	0
Respiratory, thoracic and mediastinal disorders			
ATELECTASIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
COUGH			
subjects affected / exposed	24 / 201 (11.94%)	8 / 31 (25.81%)	2 / 20 (10.00%)
occurrences (all)	27	10	2
DYSPHONIA			
subjects affected / exposed	4 / 201 (1.99%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	4	2	0

DYSPNOEA			
subjects affected / exposed	27 / 201 (13.43%)	9 / 31 (29.03%)	1 / 20 (5.00%)
occurrences (all)	35	10	1
DYSPNOEA EXERTIONAL			
subjects affected / exposed	4 / 201 (1.99%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	4	1	0
EPISTAXIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
HAEMOPTYSIS			
subjects affected / exposed	8 / 201 (3.98%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	10	0	0
HICCUPS			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
HYPOXIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	9 / 201 (4.48%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	9	0	0
PLEURAL EFFUSION			
subjects affected / exposed	2 / 201 (1.00%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	2	2	0
PLEURITIC PAIN			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
PNEUMONITIS			
subjects affected / exposed	1 / 201 (0.50%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
PNEUMOTHORAX			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

PRODUCTIVE COUGH			
subjects affected / exposed	10 / 201 (4.98%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	13	1	0
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RHINORRHOEA			
subjects affected / exposed	3 / 201 (1.49%)	3 / 31 (9.68%)	0 / 20 (0.00%)
occurrences (all)	4	3	0
SINUS CONGESTION			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
SNEEZING			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	4	0	1
Psychiatric disorders			
AGITATION			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	5	0	1
ANXIETY			
subjects affected / exposed	7 / 201 (3.48%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	7	0	1
CONFUSIONAL STATE			
subjects affected / exposed	8 / 201 (3.98%)	4 / 31 (12.90%)	3 / 20 (15.00%)
occurrences (all)	10	4	3
DELIRIUM			

subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
DEPRESSION			
subjects affected / exposed	8 / 201 (3.98%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	8	0	0
INSOMNIA			
subjects affected / exposed	20 / 201 (9.95%)	1 / 31 (3.23%)	2 / 20 (10.00%)
occurrences (all)	22	1	2
IRRITABILITY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
LIBIDO DECREASED			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RESTLESSNESS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	4 / 201 (1.99%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	6	2	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	17 / 201 (8.46%)	6 / 31 (19.35%)	1 / 20 (5.00%)
occurrences (all)	21	14	1
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	17 / 201 (8.46%)	5 / 31 (16.13%)	0 / 20 (0.00%)
occurrences (all)	21	13	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	11 / 201 (5.47%)	5 / 31 (16.13%)	0 / 20 (0.00%)
occurrences (all)	12	12	0

BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	5 / 201 (2.49%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	8	3	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	21 / 201 (10.45%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	27	0	0
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN INCREASED			
subjects affected / exposed	1 / 201 (0.50%)	3 / 31 (9.68%)	0 / 20 (0.00%)
occurrences (all)	1	3	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
BLOOD THYROID STIMULATING HORMONE DECREASED			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
CORTISOL DECREASED			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	11 / 201 (5.47%)	7 / 31 (22.58%)	0 / 20 (0.00%)
occurrences (all)	14	15	0
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	6	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	1 / 20 (5.00%)
occurrences (all)	3	2	1
TRANSAMINASES INCREASED			
subjects affected / exposed	2 / 201 (1.00%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	2	3	0
VITAMIN D DECREASED			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	16 / 201 (7.96%)	6 / 31 (19.35%)	1 / 20 (5.00%)
occurrences (all)	19	8	1
WEIGHT INCREASED			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
FALL			
subjects affected / exposed	6 / 201 (2.99%)	0 / 31 (0.00%)	2 / 20 (10.00%)
occurrences (all)	7	0	3
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 201 (0.50%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
POST-TRAUMATIC PAIN			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
PROCEDURAL PAIN			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
SCAR			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
SOFT TISSUE INJURY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SPINAL COLUMN INJURY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	5	0	0
EXTRASYSTOLES			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
AMNESIA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
APHASIA			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
ATAXIA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	2
BRAIN OEDEMA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
COGNITIVE DISORDER			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
DIZZINESS			
subjects affected / exposed	11 / 201 (5.47%)	5 / 31 (16.13%)	2 / 20 (10.00%)
occurrences (all)	14	5	3
DIZZINESS POSTURAL			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSARTHRIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	3 / 201 (1.49%)	2 / 31 (6.45%)	1 / 20 (5.00%)
occurrences (all)	3	2	1
EXTRAPYRAMIDAL DISORDER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
HEADACHE			
subjects affected / exposed	10 / 201 (4.98%)	7 / 31 (22.58%)	9 / 20 (45.00%)
occurrences (all)	15	7	11
HEMIPARESIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
HYPOAESTHESIA			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
LETHARGY			

subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
NEUROPATHY PERIPHERAL			
subjects affected / exposed	9 / 201 (4.48%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	10	2	0
PARAESTHESIA			
subjects affected / exposed	1 / 201 (0.50%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
PAROSMIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
SOMNOLENCE			
subjects affected / exposed	1 / 201 (0.50%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
SYNCOPE			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
VISUAL FIELD DEFECT			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	43 / 201 (21.39%)	4 / 31 (12.90%)	2 / 20 (10.00%)
occurrences (all)	72	7	2
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
NEUTROPENIA			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	5	0	1
SPLENOMEGALY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	5 / 201 (2.49%)	1 / 31 (3.23%)	1 / 20 (5.00%)
occurrences (all)	9	1	1
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EUSTACHIAN TUBE DYSFUNCTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
OTORRHOEA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
TINNITUS			

subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Eye disorders			
CATARACT			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
CONJUNCTIVAL HYPERAEMIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DIPLOPIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
EYE PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
REFRACTION DISORDER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
VISION BLURRED			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
VITREOUS FLOATERS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
ABDOMINAL DISTENSION			
subjects affected / exposed	6 / 201 (2.99%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	6	1	0
ABDOMINAL PAIN			

subjects affected / exposed	20 / 201 (9.95%)	9 / 31 (29.03%)	1 / 20 (5.00%)
occurrences (all)	25	12	1
ABDOMINAL PAIN LOWER			
subjects affected / exposed	3 / 201 (1.49%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	3	1	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	5 / 201 (2.49%)	1 / 31 (3.23%)	3 / 20 (15.00%)
occurrences (all)	5	1	3
ANAL INCONTINENCE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
ASCITES			
subjects affected / exposed	2 / 201 (1.00%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	2	2	0
CONSTIPATION			
subjects affected / exposed	55 / 201 (27.36%)	9 / 31 (29.03%)	2 / 20 (10.00%)
occurrences (all)	63	10	2
DIARRHOEA			
subjects affected / exposed	36 / 201 (17.91%)	4 / 31 (12.90%)	1 / 20 (5.00%)
occurrences (all)	52	5	2
DRY MOUTH			
subjects affected / exposed	11 / 201 (5.47%)	4 / 31 (12.90%)	0 / 20 (0.00%)
occurrences (all)	14	4	0
DYSPEPSIA			
subjects affected / exposed	12 / 201 (5.97%)	2 / 31 (6.45%)	1 / 20 (5.00%)
occurrences (all)	12	2	1
DYSPHAGIA			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
ERUCTATION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FAECALOMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
FLATULENCE			

subjects affected / exposed	1 / 201 (0.50%)	4 / 31 (12.90%)	0 / 20 (0.00%)
occurrences (all)	1	4	0
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	4 / 201 (1.99%)	5 / 31 (16.13%)	0 / 20 (0.00%)
occurrences (all)	4	5	0
IMPAIRED GASTRIC EMPTYING			
subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
LOOSE TOOTH			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	47 / 201 (23.38%)	10 / 31 (32.26%)	5 / 20 (25.00%)
occurrences (all)	70	15	6
ORAL PAIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	7 / 201 (3.48%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	7	1	0
TOOTHACHE			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
VOMITING			
subjects affected / exposed	27 / 201 (13.43%)	8 / 31 (25.81%)	3 / 20 (15.00%)
occurrences (all)	39	16	4
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HEPATIC PAIN			

subjects affected / exposed	0 / 201 (0.00%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
HEPATOMEGALY			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	1 / 201 (0.50%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	1	5	0
JAUNDICE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
OCULAR ICTERUS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
DRY SKIN			
subjects affected / exposed	7 / 201 (3.48%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	7	2	0
ECZEMA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ERYTHEMA			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

HYPERHIDROSIS			
subjects affected / exposed	3 / 201 (1.49%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	3	2	0
NIGHT SWEATS			
subjects affected / exposed	7 / 201 (3.48%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	9	1	0
PAIN OF SKIN			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PEMPHIGOID			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PRURITUS			
subjects affected / exposed	15 / 201 (7.46%)	5 / 31 (16.13%)	0 / 20 (0.00%)
occurrences (all)	20	8	0
PSORIASIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
RASH			
subjects affected / exposed	23 / 201 (11.44%)	4 / 31 (12.90%)	1 / 20 (5.00%)
occurrences (all)	28	6	1
RASH MACULO-PAPULAR			
subjects affected / exposed	5 / 201 (2.49%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	13	1	0
VITILIGO			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	8 / 201 (3.98%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	14	0	0
AUTOIMMUNE NEPHRITIS			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
DYSURIA			
subjects affected / exposed	6 / 201 (2.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	6	0	0
HAEMATURIA			
subjects affected / exposed	18 / 201 (8.96%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	28	0	0
NOCTURIA			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
POLLAKIURIA			
subjects affected / exposed	3 / 201 (1.49%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	3	1	0
POLYURIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
URINARY INCONTINENCE			
subjects affected / exposed	5 / 201 (2.49%)	0 / 31 (0.00%)	2 / 20 (10.00%)
occurrences (all)	5	0	2
URINARY TRACT PAIN			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	8 / 201 (3.98%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	10	0	0
HYPOTHYROIDISM			
subjects affected / exposed	17 / 201 (8.46%)	5 / 31 (16.13%)	2 / 20 (10.00%)
occurrences (all)	21	6	2
Musculoskeletal and connective tissue disorders			

ARTHRALGIA			
subjects affected / exposed	25 / 201 (12.44%)	3 / 31 (9.68%)	1 / 20 (5.00%)
occurrences (all)	40	3	2
BACK PAIN			
subjects affected / exposed	30 / 201 (14.93%)	8 / 31 (25.81%)	2 / 20 (10.00%)
occurrences (all)	44	8	2
COCCYDYNIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	9 / 201 (4.48%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	9	0	0
FOOT DEFORMITY			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GROIN PAIN			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
JOINT SWELLING			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	7 / 201 (3.48%)	3 / 31 (9.68%)	0 / 20 (0.00%)
occurrences (all)	10	3	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
MUSCULAR WEAKNESS			
subjects affected / exposed	2 / 201 (1.00%)	1 / 31 (3.23%)	2 / 20 (10.00%)
occurrences (all)	3	1	2
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	5 / 201 (2.49%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	8	1	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	16 / 201 (7.96%)	2 / 31 (6.45%)	1 / 20 (5.00%)
occurrences (all)	23	2	1

MYALGIA			
subjects affected / exposed	14 / 201 (6.97%)	3 / 31 (9.68%)	1 / 20 (5.00%)
occurrences (all)	23	4	1
NECK PAIN			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	11 / 201 (5.47%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	15	0	1
PAIN IN JAW			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
SYNOVIAL CYST			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ACUTE SINUSITIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
BRONCHITIS			
subjects affected / exposed	3 / 201 (1.49%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
CANDIDA INFECTION			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	4	0	0
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
EYE INFECTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
GASTROENTERITIS			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	9 / 201 (4.48%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	12	0	0
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	4 / 201 (1.99%)	1 / 31 (3.23%)	1 / 20 (5.00%)
occurrences (all)	4	1	1
OTITIS EXTERNA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
PNEUMONIA			
subjects affected / exposed	5 / 201 (2.49%)	1 / 31 (3.23%)	1 / 20 (5.00%)
occurrences (all)	6	1	1
PYURIA			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
RHINITIS			
subjects affected / exposed	2 / 201 (1.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
SINUSITIS			
subjects affected / exposed	4 / 201 (1.99%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	6	0	0
SKIN INFECTION			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	3 / 201 (1.49%)	1 / 31 (3.23%)	1 / 20 (5.00%)
occurrences (all)	4	1	1
URINARY TRACT INFECTION			
subjects affected / exposed	35 / 201 (17.41%)	3 / 31 (9.68%)	0 / 20 (0.00%)
occurrences (all)	55	3	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	51 / 201 (25.37%)	11 / 31 (35.48%)	4 / 20 (20.00%)
occurrences (all)	60	12	5
DEHYDRATION			
subjects affected / exposed	9 / 201 (4.48%)	5 / 31 (16.13%)	2 / 20 (10.00%)
occurrences (all)	12	6	2
FLUID INTAKE REDUCED			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			

subjects affected / exposed	10 / 201 (4.98%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	15	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	6 / 201 (2.99%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	6	2	0
HYPERKALAEMIA			
subjects affected / exposed	15 / 201 (7.46%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	20	0	0
HYPERURICAEMIA			
subjects affected / exposed	9 / 201 (4.48%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	9	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	9 / 201 (4.48%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	10	2	0
HYPOCALCAEMIA			
subjects affected / exposed	1 / 201 (0.50%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
HYPOGLYCAEMIA			
subjects affected / exposed	1 / 201 (0.50%)	1 / 31 (3.23%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
HYPOKALAEMIA			
subjects affected / exposed	11 / 201 (5.47%)	1 / 31 (3.23%)	3 / 20 (15.00%)
occurrences (all)	13	1	3
HYPOMAGNESAEMIA			
subjects affected / exposed	12 / 201 (5.97%)	2 / 31 (6.45%)	0 / 20 (0.00%)
occurrences (all)	15	3	0
HYPONATRAEMIA			
subjects affected / exposed	20 / 201 (9.95%)	3 / 31 (9.68%)	0 / 20 (0.00%)
occurrences (all)	25	3	0
IRON DEFICIENCY			
subjects affected / exposed	1 / 201 (0.50%)	0 / 31 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
POLYDIPSIA			
subjects affected / exposed	0 / 201 (0.00%)	0 / 31 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Expansion STS Cohort (MEDI4736 10 mg/kg Q2W)	Expansion OC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion MSI-high Cancer Cohort (MEDI4736 10 mg/kg Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)	46 / 47 (97.87%)	57 / 62 (91.94%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
PERITUMOURAL OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
TUMOUR PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	2 / 62 (3.23%)
occurrences (all)	0	1	2
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	3 / 20 (15.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	3	1	1
HYPERTENSION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	1	0	2
HYPOTENSION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	3 / 62 (4.84%)
occurrences (all)	0	1	3
LYMPHOEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	1	2
General disorders and administration site conditions			

ASTHENIA			
subjects affected / exposed	1 / 20 (5.00%)	4 / 47 (8.51%)	10 / 62 (16.13%)
occurrences (all)	1	6	12
CHEST DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
CHEST PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
CHILLS			
subjects affected / exposed	1 / 20 (5.00%)	4 / 47 (8.51%)	2 / 62 (3.23%)
occurrences (all)	1	4	3
EARLY SATIETY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	2	0	1
FACE OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
FATIGUE			
subjects affected / exposed	9 / 20 (45.00%)	19 / 47 (40.43%)	15 / 62 (24.19%)
occurrences (all)	11	23	19
GAIT DISTURBANCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
GENERALISED OEDEMA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
HERNIA PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			

subjects affected / exposed	1 / 20 (5.00%)	7 / 47 (14.89%)	0 / 62 (0.00%)
occurrences (all)	1	8	0
MALAISE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	2 / 62 (3.23%)
occurrences (all)	0	1	2
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	4	0
OEDEMA PERIPHERAL			
subjects affected / exposed	3 / 20 (15.00%)	9 / 47 (19.15%)	7 / 62 (11.29%)
occurrences (all)	3	12	11
PAIN			
subjects affected / exposed	0 / 20 (0.00%)	3 / 47 (6.38%)	3 / 62 (4.84%)
occurrences (all)	0	3	3
PERIPHERAL SWELLING			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
PYREXIA			
subjects affected / exposed	5 / 20 (25.00%)	8 / 47 (17.02%)	11 / 62 (17.74%)
occurrences (all)	8	8	22
SWELLING FACE			
subjects affected / exposed	1 / 20 (5.00%)	1 / 47 (2.13%)	2 / 62 (3.23%)
occurrences (all)	1	1	2
TEMPERATURE INTOLERANCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
THIRST			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
BREAST PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
BREAST TENDERNESS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
PELVIC PAIN			
subjects affected / exposed	0 / 20 (0.00%)	2 / 47 (4.26%)	1 / 62 (1.61%)
occurrences (all)	0	2	1
Respiratory, thoracic and mediastinal disorders			
ATELECTASIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	2 / 20 (10.00%)	1 / 47 (2.13%)	10 / 62 (16.13%)
occurrences (all)	2	2	13
DYSPHONIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	3 / 62 (4.84%)
occurrences (all)	1	0	3
DYSPNOEA			
subjects affected / exposed	5 / 20 (25.00%)	9 / 47 (19.15%)	5 / 62 (8.06%)
occurrences (all)	5	10	5
DYSPNOEA EXERTIONAL			
subjects affected / exposed	1 / 20 (5.00%)	3 / 47 (6.38%)	0 / 62 (0.00%)
occurrences (all)	2	4	0
EPISTAXIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	2	3
HAEMOPTYSIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	2	1
HICCUPS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
HYPOXIA			

subjects affected / exposed	1 / 20 (5.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	1	1	0
NASAL CONGESTION			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	4 / 62 (6.45%)
occurrences (all)	1	2	9
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	2 / 47 (4.26%)	3 / 62 (4.84%)
occurrences (all)	0	2	3
PLEURAL EFFUSION			
subjects affected / exposed	2 / 20 (10.00%)	4 / 47 (8.51%)	1 / 62 (1.61%)
occurrences (all)	2	5	1
PLEURITIC PAIN			
subjects affected / exposed	2 / 20 (10.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	2	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
PNEUMOTHORAX			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 20 (0.00%)	2 / 47 (4.26%)	1 / 62 (1.61%)
occurrences (all)	0	2	1
RESPIRATORY DISTRESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
RHINITIS ALLERGIC			
subjects affected / exposed	1 / 20 (5.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	1	1	1
RHINORRHOEA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
SINUS CONGESTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
SNEEZING			

subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
WHEEZING			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	0 / 62 (0.00%)
occurrences (all)	1	2	0
Psychiatric disorders			
AGITATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
ANXIETY			
subjects affected / exposed	1 / 20 (5.00%)	4 / 47 (8.51%)	8 / 62 (12.90%)
occurrences (all)	1	4	9
CONFUSIONAL STATE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
DELIRIUM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	2 / 62 (3.23%)
occurrences (all)	1	2	2
INSOMNIA			
subjects affected / exposed	0 / 20 (0.00%)	4 / 47 (8.51%)	7 / 62 (11.29%)
occurrences (all)	0	4	10
IRRITABILITY			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
LIBIDO DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
RESTLESSNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	7 / 47 (14.89%)	5 / 62 (8.06%)
occurrences (all)	2	8	9
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	5 / 47 (10.64%)	5 / 62 (8.06%)
occurrences (all)	1	6	11
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	3 / 20 (15.00%)	4 / 47 (8.51%)	4 / 62 (6.45%)
occurrences (all)	4	6	8
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	2 / 62 (3.23%)
occurrences (all)	1	2	3
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
BLOOD CREATININE INCREASED			
subjects affected / exposed	2 / 20 (10.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	2	1	2
BLOOD ELECTROLYTES DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
BLOOD FIBRINOGEN INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			

subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
BLOOD MAGNESIUM DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	1	1	0
BLOOD THYROID STIMULATING HORMONE DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
subjects affected / exposed	2 / 20 (10.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	2	0	0
CORTISOL DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	2 / 20 (10.00%)	4 / 47 (8.51%)	4 / 62 (6.45%)
occurrences (all)	3	7	10
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	1 / 62 (1.61%)
occurrences (all)	2	2	1
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	1	0	2
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	1 / 20 (5.00%)	9 / 47 (19.15%)	4 / 62 (6.45%)
occurrences (all)	3	13	7
WEIGHT INCREASED			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
FALL			
subjects affected / exposed	0 / 20 (0.00%)	3 / 47 (6.38%)	1 / 62 (1.61%)
occurrences (all)	0	3	1
INFUSION RELATED REACTION			
subjects affected / exposed	2 / 20 (10.00%)	2 / 47 (4.26%)	2 / 62 (3.23%)
occurrences (all)	3	2	2
POST-TRAUMATIC PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	2 / 47 (4.26%)	1 / 62 (1.61%)
occurrences (all)	0	2	1
SCAR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
SOFT TISSUE INJURY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
SPINAL COLUMN INJURY			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
EXTRASYSTOLES			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	2	0	0
SINUS TACHYCARDIA			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	0 / 62 (0.00%)
occurrences (all)	1	2	0
Nervous system disorders			
AMNESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
APHASIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
ATAXIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
BRAIN OEDEMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
COGNITIVE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	1 / 20 (5.00%)	5 / 47 (10.64%)	5 / 62 (8.06%)
occurrences (all)	1	5	9
DIZZINESS POSTURAL			

subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
DYSARTHRIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
DYSGEUSIA			
subjects affected / exposed	0 / 20 (0.00%)	2 / 47 (4.26%)	1 / 62 (1.61%)
occurrences (all)	0	2	1
EXTRAPYRAMIDAL DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
HEADACHE			
subjects affected / exposed	2 / 20 (10.00%)	6 / 47 (12.77%)	9 / 62 (14.52%)
occurrences (all)	2	7	14
HEMIPARESIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
HYPOAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
LETHARGY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
MEMORY IMPAIRMENT			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	1	0	2
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	2 / 20 (10.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	2	1	0
PARAESTHESIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	4 / 62 (6.45%)
occurrences (all)	0	1	4
PAROSMIA			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	3 / 62 (4.84%)
occurrences (all)	0	0	3
SOMNOLENCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
TASTE DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
TREMOR			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
VISUAL FIELD DEFECT			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	8 / 20 (40.00%)	10 / 47 (21.28%)	11 / 62 (17.74%)
occurrences (all)	14	12	22
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
NEUTROPENIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

SPLENOMEGALY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 20 (5.00%)	3 / 47 (6.38%)	0 / 62 (0.00%)
occurrences (all)	2	4	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
EUSTACHIAN TUBE DYSFUNCTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
HYPOACUSIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	1	0	1
OTORRHOEA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
TINNITUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVAL HYPERAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
DIPLOPIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
DRY EYE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	0	0	2
EYE PAIN			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
REFRACTION DISORDER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
VISION BLURRED			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	3 / 62 (4.84%)
occurrences (all)	1	2	4
VITREOUS FLOATERS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 20 (0.00%)	3 / 47 (6.38%)	0 / 62 (0.00%)
occurrences (all)	0	3	0
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	3 / 62 (4.84%)
occurrences (all)	2	2	3
ABDOMINAL PAIN			
subjects affected / exposed	3 / 20 (15.00%)	15 / 47 (31.91%)	12 / 62 (19.35%)
occurrences (all)	5	23	24
ABDOMINAL PAIN LOWER			
subjects affected / exposed	2 / 20 (10.00%)	0 / 47 (0.00%)	3 / 62 (4.84%)
occurrences (all)	3	0	3
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 20 (5.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	2	5	1
ANAL INCONTINENCE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
ASCITES			
subjects affected / exposed	0 / 20 (0.00%)	7 / 47 (14.89%)	0 / 62 (0.00%)
occurrences (all)	0	11	0
CONSTIPATION			
subjects affected / exposed	3 / 20 (15.00%)	14 / 47 (29.79%)	13 / 62 (20.97%)
occurrences (all)	3	16	18

DIARRHOEA			
subjects affected / exposed	1 / 20 (5.00%)	11 / 47 (23.40%)	18 / 62 (29.03%)
occurrences (all)	1	17	37
DRY MOUTH			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	5 / 62 (8.06%)
occurrences (all)	0	1	5
DYSPEPSIA			
subjects affected / exposed	0 / 20 (0.00%)	5 / 47 (10.64%)	1 / 62 (1.61%)
occurrences (all)	0	5	1
DYSPHAGIA			
subjects affected / exposed	1 / 20 (5.00%)	1 / 47 (2.13%)	3 / 62 (4.84%)
occurrences (all)	1	1	3
ERUCTATION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
FAECALOMA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
FLATULENCE			
subjects affected / exposed	0 / 20 (0.00%)	2 / 47 (4.26%)	1 / 62 (1.61%)
occurrences (all)	0	2	1
GASTROINTESTINAL PAIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 20 (0.00%)	3 / 47 (6.38%)	3 / 62 (4.84%)
occurrences (all)	0	3	3
IMPAIRED GASTRIC EMPTYING			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
LOOSE TOOTH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
NAUSEA			

subjects affected / exposed	2 / 20 (10.00%)	15 / 47 (31.91%)	18 / 62 (29.03%)
occurrences (all)	2	25	30
ORAL PAIN			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
STOMATITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	2	1
TOOTHACHE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	2 / 62 (3.23%)
occurrences (all)	0	1	2
VOMITING			
subjects affected / exposed	2 / 20 (10.00%)	10 / 47 (21.28%)	8 / 62 (12.90%)
occurrences (all)	3	15	15
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
HEPATIC PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	0	0	2
HEPATOMEGALY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
JAUNDICE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
OCULAR ICTERUS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACNE			

subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 20 (0.00%)	3 / 47 (6.38%)	3 / 62 (4.84%)
occurrences (all)	0	3	3
ECZEMA			
subjects affected / exposed	1 / 20 (5.00%)	1 / 47 (2.13%)	2 / 62 (3.23%)
occurrences (all)	1	1	3
ERYTHEMA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	2 / 62 (3.23%)
occurrences (all)	0	1	2
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
NIGHT SWEATS			
subjects affected / exposed	2 / 20 (10.00%)	1 / 47 (2.13%)	3 / 62 (4.84%)
occurrences (all)	2	1	3
PAIN OF SKIN			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
PEMPHIGOID			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
PETECHIAE			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
PRURITUS			

subjects affected / exposed	3 / 20 (15.00%)	7 / 47 (14.89%)	10 / 62 (16.13%)
occurrences (all)	3	10	12
PSORIASIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	3	0	1
RASH			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	3 / 62 (4.84%)
occurrences (all)	1	2	3
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	5 / 62 (8.06%)
occurrences (all)	0	1	5
VITILIGO			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 20 (0.00%)	2 / 47 (4.26%)	5 / 62 (8.06%)
occurrences (all)	0	2	5
AUTOIMMUNE NEPHRITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
DYSURIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	2 / 62 (3.23%)
occurrences (all)	0	1	2
HAEMATURIA			
subjects affected / exposed	0 / 20 (0.00%)	3 / 47 (6.38%)	2 / 62 (3.23%)
occurrences (all)	0	3	4
NOCTURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
POLLAKIURIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
POLYURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

PROTEINURIA			
subjects affected / exposed	0 / 20 (0.00%)	3 / 47 (6.38%)	1 / 62 (1.61%)
occurrences (all)	0	4	2
URINARY INCONTINENCE			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
URINARY TRACT PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
HYPOTHYROIDISM			
subjects affected / exposed	2 / 20 (10.00%)	4 / 47 (8.51%)	6 / 62 (9.68%)
occurrences (all)	3	4	6
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	5 / 20 (25.00%)	11 / 47 (23.40%)	9 / 62 (14.52%)
occurrences (all)	6	15	14
BACK PAIN			
subjects affected / exposed	4 / 20 (20.00%)	8 / 47 (17.02%)	14 / 62 (22.58%)
occurrences (all)	5	8	20
COCCYDYNIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
FLANK PAIN			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	0 / 62 (0.00%)
occurrences (all)	1	2	0
FOOT DEFORMITY			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
GROIN PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
JOINT SWELLING			

subjects affected / exposed	0 / 20 (0.00%)	3 / 47 (6.38%)	1 / 62 (1.61%)
occurrences (all)	0	4	1
MUSCLE SPASMS			
subjects affected / exposed	1 / 20 (5.00%)	2 / 47 (4.26%)	0 / 62 (0.00%)
occurrences (all)	1	2	0
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	4 / 20 (20.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	4	1	1
MUSCULOSKELETAL PAIN			
subjects affected / exposed	3 / 20 (15.00%)	3 / 47 (6.38%)	3 / 62 (4.84%)
occurrences (all)	3	4	4
MYALGIA			
subjects affected / exposed	0 / 20 (0.00%)	4 / 47 (8.51%)	5 / 62 (8.06%)
occurrences (all)	0	5	6
NECK PAIN			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
PAIN IN EXTREMITY			
subjects affected / exposed	4 / 20 (20.00%)	1 / 47 (2.13%)	3 / 62 (4.84%)
occurrences (all)	4	1	3
PAIN IN JAW			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
SYNOVIAL CYST			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
ACUTE SINUSITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

BRONCHITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	1	0	2
CANDIDA INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
EYE INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	2	0	0
GASTROENTERITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	1	0	1
GINGIVITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
HERPES ZOSTER			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	4 / 62 (6.45%)
occurrences (all)	0	1	4
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			

subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	3 / 62 (4.84%)
occurrences (all)	1	0	3
OTITIS EXTERNA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	1	0	2
PNEUMONIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
PYURIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
RHINITIS			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	3 / 62 (4.84%)
occurrences (all)	2	0	3
SINUSITIS			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	0	0	2
SKIN INFECTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	0	0	2
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	4 / 47 (8.51%)	8 / 62 (12.90%)
occurrences (all)	1	4	8
URINARY TRACT INFECTION			
subjects affected / exposed	4 / 20 (20.00%)	8 / 47 (17.02%)	10 / 62 (16.13%)
occurrences (all)	7	8	14

VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	1 / 62 (1.61%)
occurrences (all)	1	0	2
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	2 / 20 (10.00%)	14 / 47 (29.79%)	10 / 62 (16.13%)
occurrences (all)	3	17	14
DEHYDRATION			
subjects affected / exposed	1 / 20 (5.00%)	5 / 47 (10.64%)	4 / 62 (6.45%)
occurrences (all)	1	5	4
FLUID INTAKE REDUCED			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
FLUID RETENTION			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	2 / 62 (3.23%)
occurrences (all)	0	1	2
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	1 / 47 (2.13%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
HYPERKALAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	0	0	4
HYPERURICAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	2 / 62 (3.23%)
occurrences (all)	0	0	3
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	2 / 47 (4.26%)	3 / 62 (4.84%)
occurrences (all)	0	2	3
HYPOCALCAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	3 / 62 (4.84%)
occurrences (all)	0	0	9
HYPOGLYCAEMIA			

subjects affected / exposed	0 / 20 (0.00%)	4 / 47 (8.51%)	0 / 62 (0.00%)
occurrences (all)	0	5	0
HYPOKALAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	4 / 47 (8.51%)	6 / 62 (9.68%)
occurrences (all)	1	6	6
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 20 (0.00%)	7 / 47 (14.89%)	4 / 62 (6.45%)
occurrences (all)	0	8	8
HYPONATRAEMIA			
subjects affected / exposed	1 / 20 (5.00%)	0 / 47 (0.00%)	4 / 62 (6.45%)
occurrences (all)	1	0	4
IRON DEFICIENCY			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
POLYDIPSIA			
subjects affected / exposed	0 / 20 (0.00%)	0 / 47 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Expansion SCLC Cohort (MEDI4736 10 mg/kg Q2W)	Expansion NPC Cohort (MEDI4736 10 mg/kg Q2W)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 21 (90.48%)	10 / 10 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PERITUMOURAL OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
TUMOUR PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			

DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HOT FLUSH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HYPERTENSION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
HYPOTENSION			
subjects affected / exposed	2 / 21 (9.52%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
LYMPHOEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
CHEST DISCOMFORT			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
CHILLS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
EARLY SATIETY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
FACE OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
FATIGUE			

subjects affected / exposed	6 / 21 (28.57%)	4 / 10 (40.00%)		
occurrences (all)	7	4		
GAIT DISTURBANCE				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
GENERAL PHYSICAL HEALTH DETERIORATION				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
GENERALISED OEDEMA				
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
HERNIA PAIN				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
INFLUENZA LIKE ILLNESS				
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)		
occurrences (all)	1	0		
MALAISE				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
MUCOSAL INFLAMMATION				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
NON-CARDIAC CHEST PAIN				
subjects affected / exposed	2 / 21 (9.52%)	0 / 10 (0.00%)		
occurrences (all)	4	0		
OEDEMA PERIPHERAL				
subjects affected / exposed	2 / 21 (9.52%)	2 / 10 (20.00%)		
occurrences (all)	2	2		
PAIN				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
PERIPHERAL SWELLING				
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)		
occurrences (all)	1	0		

PYREXIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
SWELLING FACE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
TEMPERATURE INTOLERANCE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
THIRST			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
BREAST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
BREAST TENDERNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PELVIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
ATELECTASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
COUGH			
subjects affected / exposed	6 / 21 (28.57%)	2 / 10 (20.00%)	
occurrences (all)	7	4	
DYSPHONIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	

DYSPNOEA			
subjects affected / exposed	3 / 21 (14.29%)	2 / 10 (20.00%)	
occurrences (all)	3	3	
DYSPNOEA EXERTIONAL			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
EPISTAXIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HAEMOPTYSIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
HICCUPS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HYPOXIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
NASAL CONGESTION			
subjects affected / exposed	1 / 21 (4.76%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 21 (4.76%)	2 / 10 (20.00%)	
occurrences (all)	1	2	
PLEURAL EFFUSION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
PLEURITIC PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PNEUMONITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
PNEUMOTHORAX			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	

PRODUCTIVE COUGH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
RESPIRATORY DISTRESS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
RHINORRHOEA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
SINUS CONGESTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
SNEEZING			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
UPPER-AIRWAY COUGH SYNDROME			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
WHEEZING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
AGITATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
ANXIETY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
CONFUSIONAL STATE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DELIRIUM			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DEPRESSION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
INSOMNIA			
subjects affected / exposed	3 / 21 (14.29%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
IRRITABILITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
LIBIDO DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
RESTLESSNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Investigations			
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 21 (4.76%)	2 / 10 (20.00%)	
occurrences (all)	1	4	
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	

BLOOD BILIRUBIN INCREASED				
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
BLOOD CHOLESTEROL INCREASED				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
BLOOD CREATININE INCREASED				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
BLOOD ELECTROLYTES DECREASED				
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
BLOOD FIBRINOGEN INCREASED				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
BLOOD LACTATE DEHYDROGENASE INCREASED				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
BLOOD MAGNESIUM DECREASED				
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
BLOOD THYROID STIMULATING HORMONE DECREASED				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
BLOOD THYROID STIMULATING HORMONE INCREASED				
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)		
occurrences (all)	0	1		
CORTISOL DECREASED				
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)		
occurrences (all)	0	0		
GAMMA-GLUTAMYLTRANSFERASE INCREASED				
subjects affected / exposed	3 / 21 (14.29%)	1 / 10 (10.00%)		
occurrences (all)	3	1		
INTERNATIONAL NORMALISED RATIO INCREASED				

subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
VITAMIN D DECREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
WEIGHT DECREASED			
subjects affected / exposed	2 / 21 (9.52%)	2 / 10 (20.00%)	
occurrences (all)	2	2	
WEIGHT INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
FALL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
POST-TRAUMATIC PAIN			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PROCEDURAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
SCAR			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
SKIN ABRASION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
SOFT TISSUE INJURY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
SPINAL COLUMN INJURY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
EXTRASYSTOLES			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PALPITATIONS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
AMNESIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
APHASIA			

subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
ATAXIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
BRAIN OEDEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
COGNITIVE DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DIZZINESS			
subjects affected / exposed	3 / 21 (14.29%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
DIZZINESS POSTURAL			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DYSARTHRIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DYSGEUSIA			
subjects affected / exposed	0 / 21 (0.00%)	3 / 10 (30.00%)	
occurrences (all)	0	3	
EXTRAPYRAMIDAL DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HEADACHE			
subjects affected / exposed	4 / 21 (19.05%)	4 / 10 (40.00%)	
occurrences (all)	4	5	
HEMIPARESIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HYPOAESTHESIA			
subjects affected / exposed	0 / 21 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	
LETHARGY			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
MEMORY IMPAIRMENT			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
NERVOUS SYSTEM DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
PARAESTHESIA			
subjects affected / exposed	0 / 21 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	
PAROSMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PERIPHERAL MOTOR NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
SOMNOLENCE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
SYNCOPE			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
TASTE DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
TREMOR			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
VISUAL FIELD DEFECT			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	5 / 21 (23.81%)	1 / 10 (10.00%)	
occurrences (all)	5	1	
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
LEUKOPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
NEUTROPENIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
SPLENOMEGALY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 21 (4.76%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
EUSTACHIAN TUBE DYSFUNCTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
HYPOACUSIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
OTORRHOEA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
TINNITUS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
CATARACT			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
CONJUNCTIVAL HYPERAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DIPLOPIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
DRY EYE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
EYE PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
REFRACTION DISORDER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
VISION BLURRED			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
VITREOUS FLOATERS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL PAIN			

subjects affected / exposed	3 / 21 (14.29%)	3 / 10 (30.00%)	
occurrences (all)	3	3	
ABDOMINAL PAIN LOWER			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 21 (4.76%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
ANAL INCONTINENCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
ASCITES			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
CONSTIPATION			
subjects affected / exposed	4 / 21 (19.05%)	0 / 10 (0.00%)	
occurrences (all)	4	0	
DIARRHOEA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DRY MOUTH			
subjects affected / exposed	1 / 21 (4.76%)	2 / 10 (20.00%)	
occurrences (all)	1	2	
DYSPEPSIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
DYSPHAGIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
ERUCTATION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
FAECALOMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
FLATULENCE			

subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
GASTROINTESTINAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	3 / 21 (14.29%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
IMPAIRED GASTRIC EMPTYING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
LOOSE TOOTH			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
NAUSEA			
subjects affected / exposed	6 / 21 (28.57%)	3 / 10 (30.00%)	
occurrences (all)	6	3	
ORAL PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
STOMATITIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
TOOTHACHE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
VOMITING			
subjects affected / exposed	4 / 21 (19.05%)	3 / 10 (30.00%)	
occurrences (all)	5	3	
Hepatobiliary disorders			
CHOLESTASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HEPATIC PAIN			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HEPATOMEGALY			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
JAUNDICE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
OCULAR ICTERUS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DERMATITIS PSORIASIFORM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DRY SKIN			
subjects affected / exposed	1 / 21 (4.76%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
ECZEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
ERYTHEMA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
EXFOLIATIVE RASH			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	

HYPERHIDROSIS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
NIGHT SWEATS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PAIN OF SKIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PEMPHIGOID			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PETECHIAE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PRURITUS			
subjects affected / exposed	0 / 21 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	3	
PSORIASIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
RASH			
subjects affected / exposed	0 / 21 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	
RASH MACULO-PAPULAR			
subjects affected / exposed	2 / 21 (9.52%)	0 / 10 (0.00%)	
occurrences (all)	2	0	
VITILIGO			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
AUTOIMMUNE NEPHRITIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
DYSURIA			
subjects affected / exposed	2 / 21 (9.52%)	1 / 10 (10.00%)	
occurrences (all)	2	1	
HAEMATURIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
NOCTURIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
POLLAKIURIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
POLYURIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
PROTEINURIA			
subjects affected / exposed	2 / 21 (9.52%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
URINARY INCONTINENCE			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
URINARY TRACT PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HYPOTHYROIDISM			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			

ARTHRALGIA			
subjects affected / exposed	3 / 21 (14.29%)	2 / 10 (20.00%)	
occurrences (all)	3	2	
BACK PAIN			
subjects affected / exposed	4 / 21 (19.05%)	1 / 10 (10.00%)	
occurrences (all)	4	2	
COCCYDYNIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
FLANK PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
FOOT DEFORMITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
GROIN PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
JOINT SWELLING			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
MUSCLE SPASMS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
MUSCLE TIGHTNESS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 21 (4.76%)	1 / 10 (10.00%)	
occurrences (all)	1	1	

MYALGIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
NECK PAIN			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PAIN IN JAW			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
SYNOVIAL CYST			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
ACUTE SINUSITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
BRONCHITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
CANDIDA INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
EYE INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
FOLLICULITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
GASTROENTERITIS			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
GINGIVITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HERPES ZOSTER			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
INFLUENZA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
NASOPHARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 21 (0.00%)	2 / 10 (20.00%)	
occurrences (all)	0	2	
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
OTITIS EXTERNA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
OTITIS MEDIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	
PHARYNGITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
PNEUMONIA			
subjects affected / exposed	2 / 21 (9.52%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
PYURIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
RHINITIS			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
SINUSITIS			
subjects affected / exposed	1 / 21 (4.76%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
SKIN INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 21 (4.76%)	1 / 10 (10.00%)	
occurrences (all)	2	2	
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	1 / 21 (4.76%)	1 / 10 (10.00%)	
occurrences (all)	1	1	
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	4 / 21 (19.05%)	1 / 10 (10.00%)	
occurrences (all)	4	1	
DEHYDRATION			
subjects affected / exposed	1 / 21 (4.76%)	2 / 10 (20.00%)	
occurrences (all)	1	3	
FLUID INTAKE REDUCED			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
FLUID RETENTION			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HYPERCALCAEMIA			

subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	2	
HYPERKALAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HYPERURICAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HYPOALBUMINAEMIA			
subjects affected / exposed	3 / 21 (14.29%)	0 / 10 (0.00%)	
occurrences (all)	3	0	
HYPOCALCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	2	
HYPOKALAEMIA			
subjects affected / exposed	1 / 21 (4.76%)	0 / 10 (0.00%)	
occurrences (all)	1	0	
HYPOMAGNESAEMIA			
subjects affected / exposed	4 / 21 (19.05%)	0 / 10 (0.00%)	
occurrences (all)	5	0	
HYPONATRAEMIA			
subjects affected / exposed	6 / 21 (28.57%)	0 / 10 (0.00%)	
occurrences (all)	7	0	
IRON DEFICIENCY			
subjects affected / exposed	0 / 21 (0.00%)	0 / 10 (0.00%)	
occurrences (all)	0	0	
POLYDIPSIA			
subjects affected / exposed	0 / 21 (0.00%)	1 / 10 (10.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 July 2012	The first cohort was changed from sentinel participant cohort to a traditional 3 + 3 design. The first cohort was to enroll a minimum of 3 participants. The DLT evaluation period was changed to the time of first dose of durvalumab until the administration of the third dose. The DLT definition was modified to include any >= Grade 3 colitis and any >= Grade 3 immune-mediated adverse event (imAE) of rash, pruritus, or diarrhea that did not downgrade to <= Grade 2 within 3 days. The sample size was modified to reflect a total of up to approximately 110 evaluable participants and up to approximately 50 participants in the dose-escalation phase.
24 July 2012	The first immunogenicity assessment was scheduled during treatment on the day of the Dose 3 infusion.
12 June 2013	In dose-expansion phase, added tumor types of ACM, UM, HCC, SCCHN, NSCLC squamous and non-squamous histology, GEC, TNBC, and PAC and removed colorectal cancer. Changed duration of treatment from 6 months past observation of disease control plus an additional 6 months of maintenance (every 2 months) treatment to a treatment period of up to 12 months. Updated text to permit continuation of treatment in participants with confirmed PD but no signs of clinical deterioration if investigators considered that participant continued to receive benefit from treatment. Revised study objectives to support the changes to dose-expansion phase and addition of patient-reported outcome measures. Modified study-stopping criteria and withdrawal criteria. Changed antitumor activity assessment to RECIST v1.1 guidelines with modifications rather than immune-related response criteria. Removed Efficacy Evaluable Population and renamed Safety Population as As-treated Population.
04 November 2013	Increased the number of participants to be enrolled in the NSCLC cohorts. Modified inclusion criteria to define NSCLC requirements, to define the number of subjects, type of cancer and cohorts required to have PD-L1 tumor positivity, to further define disease progression, to describe requirements for NSCLC prior lines of therapy, to describe archival tumor sample requirements, to define RECIST v1.1 criteria, and to provide more details on tumor biopsy requirements.
21 May 2014	The protocol title was changed to indicate that it is a Phase 1/2 study. Increased the number of participants in the SCCHN, pancreatic adenocarcinoma, and uveal melanoma expansion cohorts. Added new expansion cohorts, a primary efficacy objective, and an exploratory efficacy objective. Updated inclusion criteria. Added pneumonitis as a potential imAE.
18 June 2014	The expanded second-line SCCHN cohort was removed.
17 November 2014	Tumoral PD-L1 requirements were changed. Criterion for untreated central nervous system metastases was clarified.
25 November 2015	The UC cohort in the dose-expansion phase was expanded.
04 February 2016	Eligibility criteria for the UC cohort were updated. PD-L1 testing requirements for the UC cohort were updated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

1022 participants were enrolled, not N=1024 indicated in participant flow. Discrepancy is due to duplicate reporting of 2 NSCLC participants once in 10mg/kg dose-escalation cohort (N=6) and again in N=302 NSCLC 10mg/kg dose expansion cohort (N=304).

Notes: