



Clinical trial results:

Study of Daratumumab in Combination with Bortezomib (VELCADE), Thalidomide, and Dexamethasone (VTD) in the First Line Treatment of Transplant Eligible Subjects with Newly Diagnosed Multiple Myeloma Summary

EudraCT number	2014-004781-15
Trial protocol	NL FR BE
Global end of trial date	01 September 2023

Results information

Result version number	v1 (current)
This version publication date	31 July 2025
First version publication date	31 July 2025
Summary attachment (see zip file)	2014-004781-15_Additional results_30June2025 (2014-004781-15_Additional results_30June2025.pdf)

Trial information

Trial identification

Sponsor protocol code	IFM2015-01/HO131/54767414MMY3006
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02541383
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Intergroupe Francophone du Myelome (IFM)
Sponsor organisation address	75 avenue Parmentier, Paris, France,
Public contact	Chief Executive Officer, Intergroupe Francophone du Myelome (IFM), IFMclinicaltrials@myelome.fr
Scientific contact	Chief Executive Officer, Intergroupe Francophone du Myelome (IFM), IFMclinicaltrials@myelome.fr

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	01 September 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 September 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate if the addition of daratumumab to Bortezomib, Thalidomide and Dexamethasone will increase the stringent complete response rate after consolidation therapy (part 1) and increase the progression free survival after daratumumab maintenance therapy (part 2) in transplant eligible participants with previously untreated Multiple Myeloma.

Protection of trial subjects:

The protocol, protocol amendments, Informed Consent Form (ICF), Investigator's Brochure, and other relevant documents (eg, advertisements) were submitted to an Institutional Review Board (IRB)/Independent Ethics Committee (IEC) by the investigator and reviewed and approved by the IRB/IEC before the study was initiated. Any amendments to the protocol required IRB/IEC approval before implementation of changes made.

As applicable according to local regulations, the protocol and all protocol amendments were reviewed and approved by each pertinent Competent Authority.

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice (GCP) and applicable regulatory requirements.

Participants or their legally acceptable representatives provided their written consent to participate in the study after having been informed about the nature and purpose of the study, participation/termination conditions, and risks and benefits of treatment. Informed consent was obtained during the Screening Phase prior to enrollment. A copy of the ICF(s) was provided to the participant or the participant's legally acceptable representative.

Personal data from participants enrolled in this study were limited to those data necessary to investigate the efficacy, safety, quality, and utility of the investigational study intervention(s) used in this study and were collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations.

An Independent Data Monitoring Committee (IDMC) reviewed safety data after 100 subjects had completed consolidation therapy. Subsequently, the IDMC was to review safety data at regular intervals during the study (ie, every 6 months).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 September 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 89
Country: Number of subjects enrolled	France: 854
Country: Number of subjects enrolled	Netherlands: 142
Worldwide total number of subjects	1085
EEA total number of subjects	1085

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)	1004
From 65 to 84 years	81
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Planned: 1080 subjects (540/arm) for first randomization (induction)

Actual: 1085 subjects randomized in the first randomization.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	VTd only

Arm description:

All patients randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), not re-randomized in maintenance phase.

Arm type	Active comparator
Investigational medicinal product name	Bortezomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1.3 mg/m² bortezomib as a subcutaneous injection twice a week (Days 1, 4, 8, and 11) for four 28-day induction cycles (Cycles 1 to 4), and two consolidation cycles (Cycles 5 and 6), with an option to change the schedule from twice a week to once a week, should toxicity be encountered. Cycles remained 28 days in length regardless of injection interval.

Investigational medicinal product name	Thalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Thalidomide was administered Per Os at 100 mg daily for 4 x28 days induction cycles and 2 x 28 days consolidation cycles. Thalidomide had to be taken as a single dose at bedtime, to reduce the impact of somnolence. Thalidomide could be taken with or without food. Breaking or dividing thalidomide was strongly discouraged.

Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone was administered at 40 mg during Cycles 1 and 2 on Days 1-2, Days 8-9, Days 15-16 and Days 22-23. In Cycles 3 and 4, dexamethasone was administered at 40 mg on Days 1-2 and 20 mg on Days 8-9 and Days 15-16. Dexamethasone 20 mg was administered in Cycles 5 and 6 on Days 1-2, Days 8-9 and Days 15-16.

Dexamethasone tablets was to be taken with or immediately after a meal or snack, preferably in the morning.

Arm title	DVTd only
<p>Arm description:</p> <p>All patients randomized to the DVTd group (Daratumumab, Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), not re-randomized in maintenance phase.</p>	
Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
<p>Dosage and administration details:</p> <p>Daratumumab (16mg/kg) was administered by intravenous (IV) infusion once every week for 8 weeks (VTD induction Cycle 1-2), then every 2 weeks for the 2 remaining induction cycles and the 2 consolidation cycles based on treatment assignment.</p>	
Investigational medicinal product name	Bortezomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use
<p>Dosage and administration details:</p> <p>Subjects received 1.3 mg/m² bortezomib as a subcutaneous injection twice a week (Days 1, 4, 8, and 11) for four 28-day induction cycles (Cycles 1 to 4), and two consolidation cycles (Cycles 5 and 6), with an option to change the schedule from twice a week to once a week, should toxicity be encountered. Cycles remained 28 days in length regardless of injection interval.</p>	
Investigational medicinal product name	Thalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use
<p>Dosage and administration details:</p> <p>Thalidomide was administered Per Os at 100 mg daily for 4 x28 days induction cycles and 2 x 28 days consolidation cycles. Thalidomide had to be taken as a single dose at bedtime, to reduce the impact of somnolence. Thalidomide could be taken with or without food. Breaking or dividing thalidomide was strongly discouraged.</p>	
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection, Tablet
Routes of administration	Intravenous use, Oral use
<p>Dosage and administration details:</p> <p>Dexamethasone was administered at 40 mg during Cycles 1 and 2 on Days 1-2, Days 8-9, Days 15-16 and Days 22-23. In Cycles 3 and 4, dexamethasone was administered at 40 mg on Days 1-2 and 20 mg on Days 8-9 and Days 15-16. Dexamethasone 20 mg was administered in Cycles 5 and 6 on Days 1-2, Days 8-9 and Days 15-16. Dexamethasone tablets was to be taken with or immediately after a meal or snack, preferably in the morning</p> <p>On daratumumab infusion days, in the induction/consolidation phase, dexamethasone could be administered intravenously 1 hour before the daratumumab infusion. On days when daratumumab was not administered, dexamethasone was administered Per Os.</p>	
Arm title	VTd-OBS
<p>Arm description:</p> <p>All patients randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to observation</p>	
Arm type	Part1:Active comparator - Part2:No Intervention

Investigational medicinal product name	Bortezomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1.3 mg/m² bortezomib as a subcutaneous injection twice a week (Days 1, 4, 8, and 11) for four 28-day induction cycles (Cycles 1 to 4), and two consolidation cycles (Cycles 5 and 6), with an option to change the schedule from twice a week to once a week, should toxicity be encountered. Cycles remained 28 days in length regardless of injection interval.

Investigational medicinal product name	Thalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Thalidomide was administered Per Os at 100 mg daily for 4 x28 days induction cycles and 2 x 28 days consolidation cycles. Thalidomide had to be taken as a single dose at bedtime, to reduce the impact of somnolence. Thalidomide could be taken with or without food. Breaking or dividing thalidomide was strongly discouraged.

Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone was administered at 40 mg during Cycles 1 and 2 on Days 1-2, Days 8-9, Days 15-16 and Days 22-23. In Cycles 3 and 4, dexamethasone was administered at 40 mg on Days 1-2 and 20 mg on Days 8-9 and Days 15-16. Dexamethasone 20 mg was administered in Cycles 5 and 6 on Days 1-2, Days 8-9 and Days 15-16.

Dexamethasone tablets was to be taken with or immediately after a meal or snack, preferably in the morning.

Arm title	VTd-DARA
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Arm description:

All patients randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to daratumumab monotherapy

Arm type	Part1:Active comparator - Part2:Experimental
Investigational medicinal product name	Bortezomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1.3 mg/m² bortezomib as a subcutaneous injection twice a week (Days 1, 4, 8, and 11) for four 28-day induction cycles (Cycles 1 to 4), and two consolidation cycles (Cycles 5 and 6), with an option to change the schedule from twice a week to once a week, should toxicity be encountered. Cycles remained 28 days in length regardless of injection interval.

Investigational medicinal product name	Thalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Thalidomide was administered Per Os at 100 mg daily for 4 x28 days induction cycles and 2 x 28 days consolidation cycles. Thalidomide had to be taken as a single dose at bedtime, to reduce the

impact of somnolence. Thalidomide could be taken with or without food. Breaking or dividing thalidomide was strongly discouraged.

Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dexamethasone was administered at 40 mg during Cycles 1 and 2 on Days 1-2, Days 8-9, Days 15-16 and Days 22-23. In Cycles 3 and 4, dexamethasone was administered at 40 mg on Days 1-2 and 20 mg on Days 8-9 and Days 15-16. Dexamethasone 20 mg was administered in Cycles 5 and 6 on Days 1-2, Days 8-9 and Days 15-16. Dexamethasone tablets was to be taken with or immediately after a meal or snack, preferably in the morning

Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Following second randomization, subjects assigned to the daratumumab maintenance arm received daratumumab (16mg/kg) once every 8 weeks until documented disease progression (limited to a maximum duration of 2 years).

Arm title	DVTd-OBS
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Arm description:

All patients randomized to the DVTd group (Daratumumab, Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to observation.

Arm type	Part1:Experimental - Part2:No Intervention
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Daratumumab (16mg/kg) was administered by intravenous (IV) infusion once every week for 8 weeks (VTD induction Cycle 1-2), then every 2 weeks for the 2 remaining induction cycles and the 2 consolidation cycles based on treatment assignment.

Investigational medicinal product name	Bortezomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1.3 mg/m² bortezomib as a subcutaneous injection twice a week (Days 1, 4, 8, and 11) for four 28-day induction cycles (Cycles 1 to 4), and two consolidation cycles (Cycles 5 and 6), with an option to change the schedule from twice a week to once a week, should toxicity be encountered. Cycles remained 28 days in length regardless of injection interval.

Investigational medicinal product name	Thalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Thalidomide was administered Per Os at 100 mg daily for 4 x28 days induction cycles and 2 x 28 days consolidation cycles. Thalidomide had to be taken as a single dose at bedtime, to reduce the

impact of somnolence. Thalidomide could be taken with or without food. Breaking or dividing thalidomide was strongly discouraged.

Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection, Tablet
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Dexamethasone was administered at 40 mg during Cycles 1 and 2 on Days 1-2, Days 8-9, Days 15-16 and Days 22-23. In Cycles 3 and 4, dexamethasone was administered at 40 mg on Days 1-2 and 20 mg on Days 8-9 and Days 15-16. Dexamethasone 20 mg was administered in Cycles 5 and 6 on Days 1-2, Days 8-9 and Days 15-16. Dexamethasone tablets was to be taken with or immediately after a meal or snack, preferably in the morning.

On daratumumab infusion days, in the induction/consolidation phase, dexamethasone could be administered intravenously 1 hour before the daratumumab infusion. On days when daratumumab was not administered, dexamethasone was administered Per Os.

Arm title	DVTd-DARA
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Arm description:

All patients randomized to the DVTd group (Daratumumab, Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to daratumumab monotherapy.

Arm type	Part1:Experimental - Part2:Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Daratumumab (16mg/kg) was administered by intravenous (IV) infusion once every week for 8 weeks (VTD induction Cycle 1-2), then every 2 weeks for the 2 remaining induction cycles and the 2 consolidation cycles.

Following second randomization, subjects assigned to the daratumumab maintenance arm received daratumumab (16mg/kg) once every 8 weeks until documented disease progression (limited to a maximum duration of 2 years).

Investigational medicinal product name	Bortezomib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 1.3 mg/m² bortezomib as a subcutaneous injection twice a week (Days 1, 4, 8, and 11) for four 28-day induction cycles (Cycles 1 to 4), and two consolidation cycles (Cycles 5 and 6), with an option to change the schedule from twice a week to once a week, should toxicity be encountered. Cycles remained 28 days in length regardless of injection interval.

Investigational medicinal product name	Thalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Thalidomide was administered Per Os at 100 mg daily for 4 x28 days induction cycles and 2 x 28 days consolidation cycles. Thalidomide had to be taken as a single dose at bedtime, to reduce the impact of somnolence. Thalidomide could be taken with or without food. Breaking or dividing thalidomide was strongly discouraged.

Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Injection, Tablet
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Dexamethasone was administered at 40 mg during Cycles 1 and 2 on Days 1-2, Days 8-9, Days 15-16 and Days 22-23. In Cycles 3 and 4, dexamethasone was administered at 40 mg on Days 1-2 and 20 mg on Days 8-9 and Days 15-16. Dexamethasone 20 mg was administered in Cycles 5 and 6 on Days 1-2, Days 8-9 and Days 15-16. Dexamethasone tablets was to be taken with or immediately after a meal or snack, preferably in the morning.

On daratumumab infusion days, in the induction/consolidation phase, dexamethasone could be administered intravenously 1 hour before the daratumumab infusion. On days when daratumumab was not administered, dexamethasone was administered Per Os.

Number of subjects in period 1	VTd only	DVTd only	VTd-OBS
Started	114	85	215
Completed	53	38	165
Not completed	61	47	50
Adverse event, serious fatal	50	37	48
Sponsor's decision	1	1	-
Consent withdrawn by subject	5	6	1
Lost to follow-up	5	3	1

Number of subjects in period 1	VTd-DARA	DVTd-OBS	DVTd-DARA
Started	213	229	229
Completed	170	205	204
Not completed	43	24	25
Adverse event, serious fatal	41	21	25
Sponsor's decision	-	-	-
Consent withdrawn by subject	1	-	-
Lost to follow-up	1	3	-

Baseline characteristics

Reporting groups

Reporting group title	VTd only
Reporting group description: All patients randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), not re-randomized in maintenance phase.	
Reporting group title	DVTd only
Reporting group description: All patients randomized to the DVTd group (Daratumumab, Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), not re-randomized in maintenance phase.	
Reporting group title	VTd-OBS
Reporting group description: All patients randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to observation	
Reporting group title	VTd-DARA
Reporting group description: All patients randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to daratumumab monotherapy	
Reporting group title	DVTd-OBS
Reporting group description: All patients randomized to the DVTd group (Daratumumab, Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to observation.	
Reporting group title	DVTd-DARA
Reporting group description: All patients randomized to the DVTd group (Daratumumab, Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to daratumumab monotherapy.	

Reporting group values	VTd only	DVTd only	VTd-OBS
Number of subjects	114	85	215
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	105	77	200
From 65 to 84 years	9	8	15
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	57.7	57.8	56
standard deviation	± 6.36	± 7.5	± 6.96
Title for Gender Units: subjects			
Female	42	37	94
Male	72	48	121

Baseline ISS Stage			
<p>The International Staging System (ISS) for Multiple Myeloma was established by the International Myeloma Working Group (IMWG) in 2005. Sβ2M = Serum β2 microglobulin.</p> <p>Stage I is defined by Sβ2M < 3.5 mg/L and serum albumin \geq 3.5 g/dL - Stage II is defined by Sβ2M < 3.5 mg/L and serum albumin < 3.5 g/dL; or Sβ2M \geq 3.5 mg/L and < 5.5 mg/L, irrespective of serum albumin - Stage III is defined by Sβ2M \geq 5.5 mg/L.</p> <p>Stage I is considered to have a better prognosis and stage III a worse prognosis.</p>			
Units: Subjects			
Stage I	47	25	88
Stage II	52	41	96
Stage III	15	19	31
Baseline Type of Myeloma			
<p>Multiple myeloma has different types of monoclonal proteins. These types are based on the immunoglobulin (protein) produced by the myeloma cell and they are identified by immunofixation method. The five types of heavy protein chains are G, A, D, E, and M.</p> <p>The two types of light protein chains are kappa (K) and lambda (λ). The myeloma cells may secrete heavy and light protein chains (i.e. IgG Kappa) but also only light protein chains.</p> <p>Row "Biclonal" = the myeloma cells (plasmocytes) produce two immunoglobulins with heavy chains.</p> <p>Row "negative immunofixation" = absence of monoclonal proteins</p>			
Units: Subjects			
Biclonal	1	2	10
IgA	15	14	46
IgD	3	1	3
IgG	79	54	126
IgM	0	0	1
Kappa	11	9	17
Lambda	3	5	10
Negative Immunofixation	2	0	2
Presence of diffuse myeloma-related osteopenia			
Units: Subjects			
No	100	76	197
Yes	14	9	18
Missing	0	0	0
Presence of evaluable bone marrow assessment			
Units: Subjects			
No	3	0	3
Yes	111	85	212
Bone marrow cellularity			
A sample of bone marrow aspirate was analyzed to count the cells and assess the cellular richness			
Units: Subjects			
Hypercellular	30	28	62
Normocellular	52	31	78
Moderately cellular	24	19	50
Severely acellular	5	3	13
Indeterminate	1	3	8
Missing	2	1	4
Time since initial diagnosis to randomization			
Units: months			
arithmetic mean	1.6	1.3	1.2
standard deviation	\pm 2.65	\pm 0.96	\pm 0.86
Reporting group values	VTd-DARA	DVTd-OBS	DVTd-DARA

Number of subjects	213	229	229
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	194	216	212
From 65 to 84 years	19	13	17
85 years and over	0	0	0
Title for AgeContinuous			
Units: years			
arithmetic mean	56.3	56.8	56.4
standard deviation	± 7.38	± 6.83	± 6.79
Title for Gender			
Units: subjects			
Female	87	96	94
Male	126	133	135
Baseline ISS Stage			
<p>The International Staging System (ISS) for Multiple Myeloma was established by the International Myeloma Working Group (IMWG) in 2005. Sβ2M = Serum β2 microglobulin.</p> <p>Stage I is defined by Sβ2M < 3.5 mg/L and serum albumin \geq 3.5 g/dL - Stage II is defined by Sβ2M < 3.5 mg/L and serum albumin < 3.5 g/dL; or Sβ2M \geq 3.5 mg/L and < 5.5 mg/L, irrespective of serum albumin - Stage III is defined by Sβ2M \geq 5.5 mg/L.</p> <p>Stage I is considered to have a better prognosis and stage III a worse prognosis.</p>			
Units: Subjects			
Stage I	93	83	96
Stage II	85	118	96
Stage III	35	28	37
Baseline Type of Myeloma			
<p>Multiple myeloma has different types of monoclonal proteins. These types are based on the immunoglobulin (protein) produced by the myeloma cell and they are identified by immunofixation method. The five types of heavy protein chains are G, A, D, E, and M.</p> <p>The two types of light protein chains are kappa (κ) and lambda (λ). The myeloma cells may secrete heavy and light protein chains (i.e. IgG Kappa) but also only light protein chains.</p> <p>Row "Biclonal" = the myeloma cells (plasmocytes) produce two immunoglobulins with heavy chains.</p> <p>Row "negative immunofixation" = absence of monoclonal proteins</p>			
Units: Subjects			
Biclonal	8	5	5
IgA	43	36	37
IgD	7	2	2
IgG	128	159	138
IgM	1	0	1
Kappa	18	17	27
Lambda	7	8	17
Negative Immunofixation	1	2	2
Presence of diffuse myeloma-related osteopenia			
Units: Subjects			
No	194	203	208
Yes	17	25	19
Missing	2	1	2
Presence of evaluable bone marrow assessment			
Units: Subjects			
No	3	4	6
Yes	210	225	223

Bone marrow cellularity			
A sample of bone marrow aspirate was analyzed to count the cells and assess the cellular richness			
Units: Subjects			
Hypercellular	63	62	46
Normocellular	93	101	112
Moderately cellular	42	41	47
Severely acellular	5	14	10
Indeterminate	8	6	8
Missing	2	5	6
Time since initial diagnosis to randomization			
Units: months			
arithmetic mean	1.2	1.2	1.2
standard deviation	± 0.87	± 1.08	± 0.95

Reporting group values	Total		
Number of subjects	1085		
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	1004		
From 65 to 84 years	81		
85 years and over	0		
Title for AgeContinuous			
Units: years			
arithmetic mean			
standard deviation	-		
Title for Gender			
Units: subjects			
Female	450		
Male	635		
Baseline ISS Stage			
<p>The International Staging System (ISS) for Multiple Myeloma was established by the International Myeloma Working Group (IMWG) in 2005. Sβ2M = Serum β2 microglobulin.</p> <p>Stage I is defined by Sβ2M < 3.5 mg/L and serum albumin \geq 3.5 g/dL - Stage II is defined by Sβ2M < 3.5 mg/L and serum albumin < 3.5 g/dL; or Sβ2M \geq 3.5 mg/L and < 5.5 mg/L, irrespective of serum albumin - Stage III is defined by Sβ2M \geq 5.5 mg/L.</p> <p>Stage I is considered to have a better prognosis and stage III a worse prognosis.</p>			
Units: Subjects			
Stage I	432		
Stage II	488		
Stage III	165		
Baseline Type of Myeloma			
<p>Multiple myeloma has different types of monoclonal proteins. These types are based on the immunoglobulin (protein) produced by the myeloma cell and they are identified by immunofixation method. The five types of heavy protein chains are G, A, D, E, and M.</p> <p>The two types of light protein chains are kappa (K) and lambda (λ). The myeloma cells may secrete heavy and light protein chains (i.e. IgG Kappa) but also only light protein chains.</p> <p>Row "Biclonal" = the myeloma cells (plasmocytes) produce two immunoglobulins with heavy chains.</p> <p>Row "negative immunofixation" = absence of monoclonal proteins</p>			
Units: Subjects			
Biclonal	31		
IgA	191		
IgD	18		

IgG	684		
IgM	3		
Kappa	99		
Lambda	50		
Negative Immunofixation	9		
Presence of diffuse myeloma-related osteopenia			
Units: Subjects			
No	978		
Yes	102		
Missing	5		
Presence of evaluable bone marrow assessment			
Units: Subjects			
No	19		
Yes	1066		
Bone marrow cellularity			
A sample of bone marrow aspirate was analyzed to count the cells and assess the cellular richness			
Units: Subjects			
Hypercellular	291		
Normocellular	467		
Moderately cellular	223		
Severely acellular	50		
Indeterminate	34		
Missing	20		
Time since initial diagnosis to randomization			
Units: months			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	VTd only
Reporting group description: All patients randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), not re-randomized in maintenance phase.	
Reporting group title	DVTd only
Reporting group description: All patients randomized to the DVTd group (Daratumumab, Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), not re-randomized in maintenance phase.	
Reporting group title	VTd-OBS
Reporting group description: All patients randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to observation	
Reporting group title	VTd-DARA
Reporting group description: All patients randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to daratumumab monotherapy	
Reporting group title	DVTd-OBS
Reporting group description: All patients randomized to the DVTd group (Daratumumab, Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to observation.	
Reporting group title	DVTd-DARA
Reporting group description: All patients randomized to the DVTd group (Daratumumab, Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (even those who didn't receive any study treatment), re-randomized to daratumumab monotherapy.	
Subject analysis set title	Set VTd Part 1
Subject analysis set type	Intention-to-treat
Subject analysis set description: Subjects allocated to the treatment "Bortezomib (VELCADE), Thalidomide, and Dexamethasone (VTd)" at the randomization 1 (part 1) Bortezomib (VELCADE), Thalidomide, and Dexamethasone (VTd): Part 1: 4 Cycles of Bortezomib, Thalidomide and Dexamethasone induction therapy, followed by Autologous Stem Cell Transplantation, followed by 2 cycles of Bortezomib, Thalidomide and Dexamethasone consolidation	
Subject analysis set title	Set VTd-Dara Part 1
Subject analysis set type	Intention-to-treat
Subject analysis set description: Subjects allocated to the treatment "Bortezomib (VELCADE), Thalidomide, and Dexamethasone (VTD) plus daratumumab" at the randomization 1 (part 1). Bortezomib, Thalidomide, Dexamethasone (VTd) + daratumumab: Part 1: 4 Cycles of Bortezomib, Thalidomide and Dexamethasone plus daratumumab 16mg/kg induction therapy, followed by Autologous Stem Cell Transplantation, followed by 2 cycles of Bortezomib, Thalidomide and Dexamethasone plus daratumumab 16 mg/kg consolidation	
Subject analysis set title	Set OBS Part 2
Subject analysis set type	Intention-to-treat
Subject analysis set description: OBS = observation All subjects randomized to the Observation group (no intervention) at randomization 2 for the maintenance phase (Part 2) whatever the treatment allocated at randomization 1	

Subject analysis set title	Set DARA Part 2
Subject analysis set type	Intention-to-treat

Subject analysis set description:

DARA = Daratumumab

All subjects randomized to the Daratumumab group at randomization 2 for the maintenance phase (Part 2), even those who didn't receive any treatment dose, and whatever the treatment allocated at randomization 1.

Daratumumab 16mg/kg every 8 weeks for 2 years.

Subject analysis set title	Set VTd Part 1 up to End of Study
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All subjects randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 whether they subsequently had randomization 2 or not, even those who didn't receive any treatment dose.

Subject analysis set title	Set VTd-Dara Part 1 up to End of Study
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All subjects randomized to the DVTd group (Daratumumab in combination with Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 whether they subsequently had randomization 2 or not, even those who didn't receive any treatment dose.

Primary: Post-Consolidation Stringent Complete Response (sCR) Rate

End point title	Post-Consolidation Stringent Complete Response (sCR) Rate
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End point description:

Post-consolidation sCR rate is defined as the percentage of ITT subjects who achieved or maintained sCR status within 30 days of Day 100 post Autologous Stem Cell Transplant (ASCT). The sCR status is assessed using the computerized algorithm according to IMWG response criteria, and must be achieved on or prior to start of subsequent therapies. Subjects must not die or progress by Day 100 post ASCT. According to the IMWG consensus recommendations for multiple myeloma treatment response criteria from 2006, the stringent complete response (sCR) was defined by a negative immunofixation on the serum and urine, and a disappearance of any soft tissue plasmacytomas, and < 5% plasma cells in bone marrow, plus normal free-light chain ratio and the absence of clonal bone marrow plasma cells by immunohistochemistry, immunofluorescence or 2- to 4- color flow cytometry.

End point type	Primary
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End point timeframe:

At day 100 post Autologous Stem Cell Transplant (ASCT), up to 114 days post ASCT

End point values	Set VTd Part 1	Set VTd-Dara Part 1		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	542	543		
Units: Subjects	110	157		

Statistical analyses

Statistical analysis title	Post-Consolidation sCR Rate
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Statistical analysis description:

sCR = Stringent Complete Response

Comparison groups	Set VTd Part 1 v Set VTd-Dara Part 1
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Number of subjects included in analysis	1085
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	2.12

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs that started during the study treatment until 30 days after the last dose of study treatment, approximately 59 months, except for secondary malignancies and deaths followed until the end of the study.

Adverse event reporting additional description:

For subjects randomized to Observation arm in the Maintenance Phase, AE were collected for 2 years after the second randomization, or upon disease progression, withdrawal of consent, death or start of new anticancer therapy (whichever occurred first in the Maintenance Phase), even though no study drug was administered.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	VTd - Part 1
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Reporting group description:

All subjects randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (whether they subsequently had randomization 2 or not) and who received at least one dose of study treatment.

Reported SAEs/AEs correspond to those considered treatment emergent (TEAE) to Part 1 only, from the first dose of study treatment to randomization 2 or subsequent therapy (ST) initiation (whichever occurred first), or after randomization 2 if TEAE related to the Part 1 treatment.

It includes deaths occurred from randomization 1 to the end of the study.

Reporting group title	DVTd - Part 1
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Reporting group description:

All subjects randomized to the DVTd group (Daratumumab in combination with Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 (whether they subsequently had randomization 2 or not) and who received at least one dose of study treatment.

Reported SAEs/AEs correspond to those considered treatment emergent (TEAE) to Part 1 only, from the first dose of study treatment to randomization 2 or subsequent therapy (ST) initiation (whichever occurred first), or after randomization 2 if TEAE related to the Part 1 treatment.

It includes deaths that occurred from randomization 1 to the end of the study.

Reporting group title	VTd-OBS - Part 2
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Reporting group description:

All subjects randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 and to observation group (OBS) at randomization 2.

Reporting of SAEs/AEs from randomization 2 for 2 years or until disease progression, withdrawal of consent, death or initiation of subsequent therapy (whichever occurred first), even though no study drug was administered during maintenance phase.

It includes deaths that occurred from randomization 2 to the end of the study. That means that all deaths reported in this group are also reported in the VTd - Part 1 group.

Reporting group title	VTd-DARA - Part 2
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Reporting group description:

All subjects randomized to the VTd group (Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 and to daratumumab group (DARA) at randomization 2.

Reported SAEs/AEs correspond to those considered treatment emergent (TEAE) to Part 2 from randomization 2 up to 30 days after the last dose of study treatment or subsequent therapy (ST) initiation (whichever occurred first).

It includes deaths that occurred from randomization 2 to the end of the study. That means that all deaths reported in this group are also reported in the VTd - Part 1 group.

Reporting group title	DVTd-OBS - Part 2
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Reporting group description:

All subjects randomized to the DVTd group (Daratumumab in combination with Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 and to observation group (OBS) at randomization 2.

Reporting of SAEs/AEs from randomization 2 for 2 years or until disease progression, withdrawal of

consent, death or initiation of subsequent therapy (whichever occurred first), even though no study drug was administered during maintenance phase.

It includes deaths that occurred from randomization 2 to the end of the study. That means that all deaths reported in this group are also reported in the DVTd - Part 1 group.

Reporting group title	DVTd-DARA - Part 2
Reporting group description:	
All subjects randomized to the DVTd group (Daratumumab in combination with Bortezomib (VELCADE), Thalidomide, and Dexamethasone) at randomization 1 and to daratumumab group (DARA) at randomization 2.	
Reported SAEs/AEs correspond to those considered treatment emergent (TEAE) to Part 2 from randomization 2 up to 30 days after the last dose of study treatment or subsequent therapy (ST) initiation (whichever occurred first).	
It includes deaths that occurred from randomization 2 to the end of the study. That means that all deaths reported in this group are also reported in the DVTd - Part 1 group.	

Serious adverse events	VTd - Part 1	DVTd - Part 1	VTd-OBS - Part 2
Total subjects affected by serious adverse events			
subjects affected / exposed	261 / 538 (48.51%)	264 / 536 (49.25%)	35 / 215 (16.28%)
number of deaths (all causes)	138	81	48
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Myeloid Leukaemia			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Adenocarcinoma of Colon			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blastic Plasmacytoid Dendritic Cell Neoplasia			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Bladder Cancer Recurrent			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Bladder Cancer			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Basal Cell Carcinoma			
subjects affected / exposed	2 / 538 (0.37%)	2 / 536 (0.37%)	2 / 215 (0.93%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaplastic Thyroid Cancer			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's Disease			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal Proliferative Breast Lesion			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 Tract Adenoma			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Breast Cancer			

subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (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
Lip Squamous Cell Carcinoma			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Natural Killer-Cell Lymphoblastic Lymphoma			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Myelodysplastic Syndrome			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Malignant Melanoma			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Cancer Metastatic			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Lung Adenocarcinoma			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Renal Oncocytoma			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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	2 / 538 (0.37%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma Cell Myeloma			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary Tumour Benign			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	1 / 538 (0.19%)	2 / 536 (0.37%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary Thyroid Cancer			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-Cell Lymphoma			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Cancer			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Vascular disorders			
Arteritis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Deep Vein Thrombosis			

subjects affected / exposed	7 / 538 (1.30%)	3 / 536 (0.56%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 / 538 (0.19%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic Hypotension			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Peripheral Artery Thrombosis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Peripheral Ischaemia			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Venous Thrombosis			
subjects affected / exposed	1 / 538 (0.19%)	2 / 536 (0.37%)	0 / 215 (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
General disorders and administration site conditions			
Chest Discomfort			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	3 / 538 (0.56%)	3 / 536 (0.56%)	0 / 215 (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
Chest Pain			
subjects affected / exposed	3 / 538 (0.56%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	2 / 538 (0.37%)	3 / 536 (0.56%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
General Physical Health Deterioration			
subjects affected / exposed	3 / 538 (0.56%)	6 / 536 (1.12%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza Like Illness			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Inflammation			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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	1 / 538 (0.19%)	2 / 536 (0.37%)	0 / 215 (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
Medical Device Site Joint Pain			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal Inflammation			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Non-Cardiac Chest Pain			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	2 / 538 (0.37%)	0 / 536 (0.00%)	0 / 215 (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
Pyrexia			
subjects affected / exposed	22 / 538 (4.09%)	15 / 536 (2.80%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 23	3 / 16	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Shock			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoidosis			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	2 / 538 (0.37%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Endometrial Hyperplasia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Erectile Dysfunction			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital Prolapse			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Uterine Cervical Metaplasia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
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 Distress Syndrome			
subjects affected / exposed	0 / 538 (0.00%)	3 / 536 (0.56%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Pulmonary Oedema			
subjects affected / exposed	1 / 538 (0.19%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Respiratory Failure			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Asthma			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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

Bronchopneumopathy			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 538 (0.00%)	3 / 536 (0.56%)	0 / 215 (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
Dyspnoea			
subjects affected / exposed	4 / 538 (0.74%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilic Pneumonia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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	1 / 538 (0.19%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic Interstitial Pneumonia			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial Lung Disease			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Disorder			

subjects affected / exposed	6 / 538 (1.12%)	10 / 536 (1.87%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 6	5 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal Oedema			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Pneumonia Aspiration			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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	2 / 538 (0.37%)	5 / 536 (0.93%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 2	2 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	20 / 538 (3.72%)	8 / 536 (1.49%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 20	1 / 8	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory Distress			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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 Polyp			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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			
Agitation			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Abnormal Behaviour			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	4 / 538 (0.74%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delusional Disorder, Unspecified Type			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Confusional State			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety Disorder			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Anxiety			
subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (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
Major Depression			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 Disorder			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device Breakage			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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			
Hepatic Enzyme Abnormal			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Physical Condition Abnormal			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Creatinine Increased			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Blood Stem Cell Harvest Failure			
subjects affected / exposed	0 / 538 (0.00%)	3 / 536 (0.56%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	2 / 538 (0.37%)	0 / 536 (0.00%)	0 / 215 (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

Femoral Neck Fracture			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns Second Degree			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured Sacrum			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion Related Reaction			

subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw Fracture			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Pelvic Fracture			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirenal Haematoma			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Preparation Error			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Complication			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Fracture			
subjects affected / exposed	3 / 538 (0.56%)	2 / 536 (0.37%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	5 / 538 (0.93%)	3 / 536 (0.56%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 Limb Fracture			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Toxicity to Various Agents			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Thoracic Vertebral Fracture			
subjects affected / exposed	3 / 538 (0.56%)	0 / 536 (0.00%)	2 / 215 (0.93%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Fanconi Syndrome			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 disorders			
Angina Pectoris			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Coronary Syndrome			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Tachycardia			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Fibrillation			
subjects affected / exposed	6 / 538 (1.12%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia Supraventricular			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			

subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Bradycardia			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Amyloidosis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	5 / 538 (0.93%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 5	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Acute			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Stenosis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Prolapse			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Paroxysmal Arrhythmia			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Myocardial Ischaemia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Pericarditis			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
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 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Tachycardia			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Ventricular Fibrillation			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute Motor-Sensory Axonal Neuropathy			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Amnestic Disorder			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Autonomic Neuropathy			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar Haematoma			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Haemorrhage			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epidural Lipomatosis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Headache			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Hemiparaesthesia			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy Peripheral			
subjects affected / exposed	1 / 538 (0.19%)	2 / 536 (0.37%)	0 / 215 (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
Neuralgia			

subjects affected / exposed	2 / 538 (0.37%)	0 / 536 (0.00%)	0 / 215 (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
Ischaemic Stroke			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	2 / 538 (0.37%)	1 / 536 (0.19%)	0 / 215 (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
Paraparesis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Motor Neuropathy			
subjects affected / exposed	2 / 538 (0.37%)	2 / 536 (0.37%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	2 / 538 (0.37%)	2 / 536 (0.37%)	0 / 215 (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
Peripheral Sensory Neuropathy			
subjects affected / exposed	16 / 538 (2.97%)	11 / 536 (2.05%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 16	0 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	4 / 538 (0.74%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior Reversible Encephalopathy Syndrome			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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	5 / 538 (0.93%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	2 / 538 (0.37%)	0 / 536 (0.00%)	0 / 215 (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
Sciatica			
subjects affected / exposed	2 / 538 (0.37%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status Epilepticus			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 538 (0.19%)	2 / 536 (0.37%)	0 / 215 (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
Transient Ischaemic Attack			
subjects affected / exposed	1 / 538 (0.19%)	2 / 536 (0.37%)	0 / 215 (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
Transient Global Amnesia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Agranulocytosis			
alternative assessment type:			

Systematic				
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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	
Eosinophilia				
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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	
Anaemia				
subjects affected / exposed	0 / 538 (0.00%)	3 / 536 (0.56%)	0 / 215 (0.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Febrile Bone Marrow Aplasia				
subjects affected / exposed	12 / 538 (2.23%)	7 / 536 (1.31%)	0 / 215 (0.00%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Febrile Neutropenia				
subjects affected / exposed	16 / 538 (2.97%)	12 / 536 (2.24%)	0 / 215 (0.00%)	
occurrences causally related to treatment / all	1 / 16	3 / 12	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Haemolytic Uraemic Syndrome				
subjects affected / exposed	2 / 538 (0.37%)	0 / 536 (0.00%)	0 / 215 (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	
Lymphopenia				
subjects affected / exposed	3 / 538 (0.56%)	7 / 536 (1.31%)	0 / 215 (0.00%)	
occurrences causally related to treatment / all	0 / 3	5 / 10	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Leukopenia				
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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	
Histiocytosis Haematophagic				

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Neutropenia			
subjects affected / exposed	8 / 538 (1.49%)	22 / 536 (4.10%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 12	12 / 22	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (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
Thrombotic Microangiopathy			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Thrombocytopenia			
subjects affected / exposed	4 / 538 (0.74%)	12 / 536 (2.24%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 4	2 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blepharitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision Blurred			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Uveitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 Fistula			
subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (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
Abdominal Pain Upper			
subjects affected / exposed	1 / 538 (0.19%)	2 / 536 (0.37%)	0 / 215 (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
Colitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Colitis Ischaemic			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Diverticular Perforation			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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	2 / 538 (0.37%)	1 / 536 (0.19%)	0 / 215 (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
Constipation			
subjects affected / exposed	3 / 538 (0.56%)	1 / 536 (0.19%)	0 / 215 (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
Colitis Ulcerative			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum Intestinal Haemorrhagic			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernial Eventration			

subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	3 / 538 (0.56%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Inguinal Hernia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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	6 / 538 (1.12%)	6 / 536 (1.12%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 6	1 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Colitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Cyst			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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 Acute			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Pneumoperitoneum			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Haemorrhage			
subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (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
Umbilical Hernia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	5 / 538 (0.93%)	4 / 536 (0.75%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Vomiting			
subjects affected / exposed	3 / 538 (0.56%)	6 / 536 (1.12%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Cholecystitis Acute			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 / 538 (0.00%)	3 / 536 (0.56%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Skin and subcutaneous tissue disorders			

Blister			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Acute Generalised Exanthematous Pustulosis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Reaction with Eosinophilia and Systemic Symptoms			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Toxic Skin Eruption			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash Maculo-Papular			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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			
Cystitis Haemorrhagic			
subjects affected / exposed	2 / 538 (0.37%)	1 / 536 (0.19%)	0 / 215 (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

Chronic Kidney Disease			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Acute Kidney Injury			
subjects affected / exposed	3 / 538 (0.56%)	3 / 536 (0.56%)	0 / 215 (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
Myeloma Cast Nephropathy			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Bladder Haemorrhage			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Tubular Necrosis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Impairment			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Failure			
subjects affected / exposed	3 / 538 (0.56%)	1 / 536 (0.19%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			

Hyperparathyroidism			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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			
Gouty Arthritis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Pain			
subjects affected / exposed	4 / 538 (0.74%)	3 / 536 (0.56%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	9 / 538 (1.67%)	9 / 536 (1.68%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteolysis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	2 / 215 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	2 / 215 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Intervertebral Disc Compression			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 Pain			
subjects affected / exposed	3 / 538 (0.56%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of Jaw			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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			
Anal Abscess			
subjects affected / exposed	3 / 538 (0.56%)	0 / 536 (0.00%)	0 / 215 (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
Bartholinitis			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Appendicitis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Arthritis Bacterial			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Bacterial Pyelonephritis			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Bronchitis			
subjects affected / exposed	1 / 538 (0.19%)	7 / 536 (1.31%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	3 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Sinusitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Cellulitis Staphylococcal			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Bronchopulmonary Aspergillosis			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Clostridium Colitis			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Clostridial Infection			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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 Sepsis			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Gastroenteritis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Cytomegalovirus Infection			
subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Oesophagitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermo-Hypodermatitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Eczema Infected			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Ear Infection			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Diverticulitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (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
Endocarditis Staphylococcal			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Bacteraemia			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr Virus Infection			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal Infection			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Sepsis			
subjects affected / exposed	3 / 538 (0.56%)	2 / 536 (0.37%)	0 / 215 (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
Fungal Oesophagitis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Salmonella			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious Colitis			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Meningitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Herpes Zoster			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective Thrombosis			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	3 / 538 (0.56%)	4 / 536 (0.75%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Discitis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Sepsis			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Legionella Infection			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Respiratory Tract Infection Viral			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Lung Infection			
subjects affected / exposed	2 / 538 (0.37%)	5 / 536 (0.93%)	3 / 215 (1.40%)
occurrences causally related to treatment / all	0 / 2	4 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus Infection			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Meningitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis Jirovecii Infection			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal Sepsis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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			
subjects affected / exposed	3 / 538 (0.56%)	0 / 536 (0.00%)	0 / 215 (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
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	4 / 538 (0.74%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Fungal			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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	9 / 538 (1.67%)	21 / 536 (3.92%)	2 / 215 (0.93%)
occurrences causally related to treatment / all	0 / 9	11 / 24	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Acinetobacter			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Bacterial			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 Escherichia			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Haemophilus			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Pneumonia Influenzal			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 Legionella			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Parainfluenzae Viral			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Pneumococcal			

subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 Pseudomonal			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Respiratory Syncytial Viral			
subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	0 / 215 (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
Pneumonia Viral			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Sepsis			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Pyelonephritis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Syncytial Virus Infection			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	11 / 538 (2.04%)	7 / 536 (1.31%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 11	1 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonella Sepsis			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 Viral			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Infection			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Infection			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Skin Bacterial Infection			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Septic Shock			

subjects affected / exposed	2 / 538 (0.37%)	4 / 536 (0.75%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	3 / 538 (0.56%)	1 / 536 (0.19%)	0 / 215 (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
Streptococcal Bacteraemia			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Streptococcal Endocarditis			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal Infection			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal Sepsis			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Systemic Mycosis			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Thrombophlebitis Septic			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
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 Infection			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Varicella			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella Zoster Virus Infection			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Viral Diarrhoea			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
subjects affected / exposed	2 / 538 (0.37%)	1 / 536 (0.19%)	0 / 215 (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
Viral Rhinitis			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cell Death			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Diabetic Metabolic Decompensation			
subjects affected / exposed	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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
Diabetes Mellitus			
subjects affected / exposed	3 / 538 (0.56%)	3 / 536 (0.56%)	0 / 215 (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
Dehydration			
subjects affected / exposed	1 / 538 (0.19%)	4 / 536 (0.75%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid Overload			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased Appetite			
subjects affected / exposed	1 / 538 (0.19%)	1 / 536 (0.19%)	0 / 215 (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
Gout			

subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid Retention			
subjects affected / exposed	2 / 538 (0.37%)	0 / 536 (0.00%)	0 / 215 (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
Hypercalcaemia			
subjects affected / exposed	0 / 538 (0.00%)	2 / 536 (0.37%)	1 / 215 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 538 (0.00%)	1 / 536 (0.19%)	0 / 215 (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
Hypokalaemia			
subjects affected / exposed	0 / 538 (0.00%)	0 / 536 (0.00%)	0 / 215 (0.00%)
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	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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	1 / 538 (0.19%)	0 / 536 (0.00%)	0 / 215 (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

Serious adverse events	VTd-DARA - Part 2	DVTd-OBS - Part 2	DVTd-DARA - Part 2
Total subjects affected by serious adverse events			
subjects affected / exposed	58 / 211 (27.49%)	50 / 229 (21.83%)	43 / 229 (18.78%)
number of deaths (all causes)	41	21	25
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Myeloid Leukaemia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 of Colon			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blastic Plasmacytoid Dendritic Cell Neoplasia			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Bladder Cancer Recurrent			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Cancer			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
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 Cell Carcinoma			
subjects affected / exposed	2 / 211 (0.95%)	0 / 229 (0.00%)	2 / 229 (0.87%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaplastic Thyroid Cancer			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's Disease			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (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

Invasive Ductal Breast Carcinoma			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal Proliferative Breast Lesion			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Tract Adenoma			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer Pain			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip Squamous Cell Carcinoma			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Natural Killer-Cell Lymphoblastic Lymphoma			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Myelodysplastic Syndrome			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Oncocytoma			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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	2 / 211 (0.95%)	1 / 229 (0.44%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma Cell Myeloma			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary Tumour Benign			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Skin			
subjects affected / exposed	2 / 211 (0.95%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary Thyroid Cancer			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-Cell Lymphoma			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Cancer			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
Arteritis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Hypotension			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Orthostatic Hypotension			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Artery Thrombosis			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Ischaemia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest Discomfort			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza Like Illness			
subjects affected / exposed	1 / 211 (0.47%)	1 / 229 (0.44%)	0 / 229 (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
Inflammation			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Malaise			

subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Site Joint Pain			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal Inflammation			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	2 / 229 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Shock			

subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Sarcoidosis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
Endometrial Hyperplasia			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Erectile Dysfunction			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Genital Prolapse			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Cervical Metaplasia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Distress Syndrome			
subjects affected / exposed	1 / 211 (0.47%)	1 / 229 (0.44%)	0 / 229 (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
Acute Pulmonary Oedema			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Respiratory Failure			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	1 / 211 (0.47%)	1 / 229 (0.44%)	0 / 229 (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
Bronchopneumopathy			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilic Pneumonia			

subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic Interstitial Pneumonia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial Lung Disease			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Disorder			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Oedema			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Distress			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Polyp			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
Agitation			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal Behaviour			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delusional Disorder, Unspecified Type			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety Disorder			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major Depression			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Mental Disorder			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Breakage			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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			
Hepatic Enzyme Abnormal			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Condition Abnormal			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
Blood Stem Cell Harvest Failure			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns Second Degree			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Fractured Sacrum			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			

subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Humerus Fracture			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw Fracture			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	1 / 211 (0.47%)	1 / 229 (0.44%)	0 / 229 (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
Overdose			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Fracture			

subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirenal Haematoma			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Preparation Error			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Rib Fracture			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Tendon Rupture			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Limb Fracture			

subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Toxicity to Various Agents			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Congenital, familial and genetic disorders			
Fanconi Syndrome			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
Angina Pectoris			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Coronary Syndrome			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
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 Tachycardia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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 Fibrillation			
subjects affected / exposed	2 / 211 (0.95%)	1 / 229 (0.44%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia Supraventricular			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Amyloidosis			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Acute			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Stenosis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paroxysmal Arrhythmia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Ischaemia			

subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial Effusion			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
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	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Supraventricular Tachycardia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Fibrillation			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute Motor-Sensory Axonal Neuropathy			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amnestic Disorder			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autonomic Neuropathy			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar Haematoma			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Haemorrhage			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Encephalopathy			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epidural Lipomatosis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparaesthesia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy Peripheral			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Sensorimotor Neuropathy			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior Reversible Encephalopathy Syndrome			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 211 (0.47%)	1 / 229 (0.44%)	2 / 229 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status Epilepticus			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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 Global Amnesia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
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 and lymphatic system disorders			
Agranulocytosis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Bone Marrow Aplasia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Febrile Neutropenia			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Haemolytic Uraemic Syndrome			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphopenia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Histiocytosis Haematophagic			
subjects affected / exposed	2 / 211 (0.95%)	0 / 229 (0.00%)	0 / 229 (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
Neutropenia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic Microangiopathy			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blepharitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision Blurred			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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	1 / 211 (0.47%)	1 / 229 (0.44%)	0 / 229 (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

Anal Fistula			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular Perforation			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Ulcerative			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum Intestinal Haemorrhagic			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernial Eventration			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			

subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Inguinal Hernia			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Colitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Cyst			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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 Acute			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Haemorrhage			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 211 (0.95%)	0 / 229 (0.00%)	0 / 229 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Acute			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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 Failure			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular Injury			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
Blister			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Generalised Exanthematous Pustulosis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Reaction with Eosinophilia and Systemic Symptoms			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic Skin Eruption			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash Maculo-Papular			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
Cystitis Haemorrhagic			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Kidney Disease			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Kidney Injury			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Myeloma Cast Nephropathy			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Colic			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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 Bladder Haemorrhage			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Tubular Necrosis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Impairment			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
Hyperparathyroidism			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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 and connective tissue disorders			
Gouty Arthritis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthralgia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteolysis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Compression			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			

subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Pain			
subjects affected / exposed	1 / 211 (0.47%)	1 / 229 (0.44%)	0 / 229 (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
Osteonecrosis of Jaw			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Arthritis Bacterial			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Pyelonephritis			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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	2 / 211 (0.95%)	1 / 229 (0.44%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Sinusitis			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis Staphylococcal			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary Aspergillosis			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Colitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Sepsis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Gastroenteritis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Oesophagitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermo-Hypodermatitis			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema Infected			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis Staphylococcal			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Bacteraemia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epstein-Barr Virus Infection			

subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Sepsis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal Oesophagitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Salmonella			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious Colitis			

subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Meningitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective Thrombosis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Intervertebral Discitis			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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 Sepsis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Legionella Infection			

subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Localised Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Infection			
subjects affected / exposed	3 / 211 (1.42%)	4 / 229 (1.75%)	3 / 229 (1.31%)
occurrences causally related to treatment / all	1 / 3	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus Infection			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis Jirovecii Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal Sepsis			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis Jirovecii Pneumonia			
subjects affected / exposed	2 / 211 (0.95%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Fungal			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (1.90%)	4 / 229 (1.75%)	7 / 229 (3.06%)
occurrences causally related to treatment / all	3 / 4	1 / 4	6 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Acinetobacter			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Bacterial			
subjects affected / exposed	2 / 211 (0.95%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Escherichia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Haemophilus			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Influenzal			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Legionella			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Parainfluenzae Viral			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Pneumococcal			
subjects affected / exposed	1 / 211 (0.47%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Pseudomonal			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Respiratory Syncytial Viral			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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 Viral			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
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 Sepsis			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Syncytial Virus Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonella Sepsis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Viral			
subjects affected / exposed	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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 / 211 (0.00%)	0 / 229 (0.00%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Infection			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 Infection			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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 Bacterial Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
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	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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
Staphylococcal Sepsis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal Bacteraemia			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal Endocarditis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal Infection			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal Sepsis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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	1 / 211 (0.47%)	0 / 229 (0.00%)	0 / 229 (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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Mycosis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis Septic			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			

subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	1 / 229 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella Zoster Virus Infection			
subjects affected / exposed	1 / 211 (0.47%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Diarrhoea			
subjects affected / exposed	0 / 211 (0.00%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Rhinitis			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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			
Cell Death			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Metabolic Decompensation			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			

subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid Overload			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased Appetite			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid Retention			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	2 / 229 (0.87%)	0 / 229 (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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
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 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	VTd - Part 1	DVTd - Part 1	VTd-OBS - Part 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	529 / 538 (98.33%)	534 / 536 (99.63%)	170 / 215 (79.07%)
Vascular disorders			
Hypertension			
subjects affected / exposed	30 / 538 (5.58%)	51 / 536 (9.51%)	4 / 215 (1.86%)
occurrences (all)	35	95	5
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	28 / 538 (5.20%)	31 / 536 (5.78%)	0 / 215 (0.00%)
occurrences (all)	33	32	0
Influenza Like Illness			
subjects affected / exposed	30 / 538 (5.58%)	34 / 536 (6.34%)	20 / 215 (9.30%)
occurrences (all)	30	39	21
Fatigue			
subjects affected / exposed	85 / 538 (15.80%)	75 / 536 (13.99%)	9 / 215 (4.19%)
occurrences (all)	117	106	9
Chills			
subjects affected / exposed	22 / 538 (4.09%)	47 / 536 (8.77%)	1 / 215 (0.47%)
occurrences (all)	22	53	1
Asthenia			

subjects affected / exposed occurrences (all)	159 / 538 (29.55%) 190	176 / 536 (32.84%) 241	27 / 215 (12.56%) 33
Malaise subjects affected / exposed occurrences (all)	25 / 538 (4.65%) 34	35 / 536 (6.53%) 37	4 / 215 (1.86%) 4
Oedema Peripheral subjects affected / exposed occurrences (all)	154 / 538 (28.62%) 206	166 / 536 (30.97%) 228	8 / 215 (3.72%) 10
Pyrexia subjects affected / exposed occurrences (all)	104 / 538 (19.33%) 128	133 / 536 (24.81%) 188	7 / 215 (3.26%) 10
Immune system disorders Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	29 / 538 (5.39%) 30	48 / 536 (8.96%) 50	7 / 215 (3.26%) 8
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	63 / 538 (11.71%) 71	78 / 536 (14.55%) 88	2 / 215 (0.93%) 2
Cough subjects affected / exposed occurrences (all)	52 / 538 (9.67%) 57	90 / 536 (16.79%) 109	19 / 215 (8.84%) 20
Dyspnoea Exertional subjects affected / exposed occurrences (all)	25 / 538 (4.65%) 29	27 / 536 (5.04%) 31	5 / 215 (2.33%) 5
Rhinorrhoea subjects affected / exposed occurrences (all)	23 / 538 (4.28%) 25	45 / 536 (8.40%) 48	6 / 215 (2.79%) 7
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	81 / 538 (15.06%) 91	64 / 536 (11.94%) 68	5 / 215 (2.33%) 5
Anxiety subjects affected / exposed occurrences (all)	47 / 538 (8.74%) 51	61 / 536 (11.38%) 75	3 / 215 (1.40%) 4
Investigations			

Weight Decreased subjects affected / exposed occurrences (all)	39 / 538 (7.25%) 40	38 / 536 (7.09%) 45	1 / 215 (0.47%) 1
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	32 / 538 (5.95%) 36	36 / 536 (6.72%) 42	1 / 215 (0.47%) 1
Paraesthesia subjects affected / exposed occurrences (all)	114 / 538 (21.19%) 161	127 / 536 (23.69%) 195	4 / 215 (1.86%) 4
Headache subjects affected / exposed occurrences (all)	42 / 538 (7.81%) 45	44 / 536 (8.21%) 50	5 / 215 (2.33%) 6
Dysgeusia subjects affected / exposed occurrences (all)	34 / 538 (6.32%) 37	50 / 536 (9.33%) 53	1 / 215 (0.47%) 2
Peripheral Sensory Neuropathy subjects affected / exposed occurrences (all)	340 / 538 (63.20%) 718	325 / 536 (60.63%) 721	24 / 215 (11.16%) 35
Tremor subjects affected / exposed occurrences (all)	58 / 538 (10.78%) 65	72 / 536 (13.43%) 88	0 / 215 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	78 / 538 (14.50%) 130	74 / 536 (13.81%) 118	7 / 215 (3.26%) 7
Febrile Neutropenia alternative assessment type: Systematic subjects affected / exposed occurrences (all)	13 / 538 (2.42%) 13	27 / 536 (5.04%) 29	1 / 215 (0.47%) 1
Neutropenia subjects affected / exposed occurrences (all)	83 / 538 (15.43%) 150	149 / 536 (27.80%) 281	6 / 215 (2.79%) 15
Lymphopenia subjects affected / exposed occurrences (all)	65 / 538 (12.08%) 211	106 / 536 (19.78%) 355	5 / 215 (2.33%) 9

Leukopenia subjects affected / exposed occurrences (all)	16 / 538 (2.97%) 23	30 / 536 (5.60%) 45	1 / 215 (0.47%) 1
Thrombocytopenia subjects affected / exposed occurrences (all)	72 / 538 (13.38%) 123	109 / 536 (20.34%) 225	4 / 215 (1.86%) 8
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	43 / 538 (7.99%) 45	40 / 536 (7.46%) 44	6 / 215 (2.79%) 6
Eye disorders Vision Blurred subjects affected / exposed occurrences (all)	31 / 538 (5.76%) 32	23 / 536 (4.29%) 24	1 / 215 (0.47%) 1
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all)	255 / 538 (47.40%) 315	271 / 536 (50.56%) 366	2 / 215 (0.93%) 2
Diarrhoea subjects affected / exposed occurrences (all)	92 / 538 (17.10%) 106	105 / 536 (19.59%) 124	10 / 215 (4.65%) 12
Abdominal Pain Upper subjects affected / exposed occurrences (all)	28 / 538 (5.20%) 28	31 / 536 (5.78%) 34	5 / 215 (2.33%) 6
Abdominal Pain subjects affected / exposed occurrences (all)	22 / 538 (4.09%) 25	36 / 536 (6.72%) 37	4 / 215 (1.86%) 4
Dry Mouth subjects affected / exposed occurrences (all)	20 / 538 (3.72%) 20	27 / 536 (5.04%) 28	2 / 215 (0.93%) 2
Nausea subjects affected / exposed occurrences (all)	129 / 538 (23.98%) 160	159 / 536 (29.66%) 209	2 / 215 (0.93%) 2
Stomatitis subjects affected / exposed occurrences (all)	102 / 538 (18.96%) 107	93 / 536 (17.35%) 104	1 / 215 (0.47%) 1
Vomiting			

subjects affected / exposed occurrences (all)	50 / 538 (9.29%) 65	83 / 536 (15.49%) 106	2 / 215 (0.93%) 2
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	7 / 538 (1.30%)	18 / 536 (3.36%)	4 / 215 (1.86%)
occurrences (all)	7	22	4
Erythema			
subjects affected / exposed	50 / 538 (9.29%)	61 / 536 (11.38%)	1 / 215 (0.47%)
occurrences (all)	60	81	1
Pruritus			
subjects affected / exposed	17 / 538 (3.16%)	25 / 536 (4.66%)	2 / 215 (0.93%)
occurrences (all)	17	29	2
Rash			
subjects affected / exposed	64 / 538 (11.90%)	80 / 536 (14.93%)	4 / 215 (1.86%)
occurrences (all)	74	95	5
Dry Skin			
subjects affected / exposed	35 / 538 (6.51%)	29 / 536 (5.41%)	2 / 215 (0.93%)
occurrences (all)	37	30	2
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	48 / 538 (8.92%)	49 / 536 (9.14%)	32 / 215 (14.88%)
occurrences (all)	58	62	37
Arthralgia			
subjects affected / exposed	28 / 538 (5.20%)	26 / 536 (4.85%)	24 / 215 (11.16%)
occurrences (all)	32	26	29
Bone Pain			
subjects affected / exposed	82 / 538 (15.24%)	68 / 536 (12.69%)	18 / 215 (8.37%)
occurrences (all)	97	84	21
Musculoskeletal Pain			
subjects affected / exposed	9 / 538 (1.67%)	17 / 536 (3.17%)	6 / 215 (2.79%)
occurrences (all)	10	18	6
Myalgia			
subjects affected / exposed	34 / 538 (6.32%)	40 / 536 (7.46%)	7 / 215 (3.26%)
occurrences (all)	38	43	7
Pain in Extremity			

subjects affected / exposed	44 / 538 (8.18%)	36 / 536 (6.72%)	3 / 215 (1.40%)
occurrences (all)	52	38	4
Muscle Spasms			
subjects affected / exposed	38 / 538 (7.06%)	33 / 536 (6.16%)	10 / 215 (4.65%)
occurrences (all)	40	39	11
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	33 / 538 (6.13%)	60 / 536 (11.19%)	20 / 215 (9.30%)
occurrences (all)	42	69	29
Herpes Zoster			
subjects affected / exposed	21 / 538 (3.90%)	27 / 536 (5.04%)	26 / 215 (12.09%)
occurrences (all)	23	28	27
Pneumonia			
subjects affected / exposed	18 / 538 (3.35%)	19 / 536 (3.54%)	6 / 215 (2.79%)
occurrences (all)	23	19	7
Bronchitis			
subjects affected / exposed	79 / 538 (14.68%)	107 / 536 (19.96%)	71 / 215 (33.02%)
occurrences (all)	94	136	100
Gastroenteritis			
subjects affected / exposed	5 / 538 (0.93%)	15 / 536 (2.80%)	13 / 215 (6.05%)
occurrences (all)	5	15	15
Rhinitis			
subjects affected / exposed	19 / 538 (3.53%)	34 / 536 (6.34%)	9 / 215 (4.19%)
occurrences (all)	19	36	10
Upper Respiratory Tract Infection			
subjects affected / exposed	20 / 538 (3.72%)	40 / 536 (7.46%)	9 / 215 (4.19%)
occurrences (all)	22	57	18
Sinusitis			
subjects affected / exposed	17 / 538 (3.16%)	20 / 536 (3.73%)	15 / 215 (6.98%)
occurrences (all)	19	25	19
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	36 / 538 (6.69%)	39 / 536 (7.28%)	2 / 215 (0.93%)
occurrences (all)	37	43	2
Hypokalaemia			

subjects affected / exposed	23 / 538 (4.28%)	31 / 536 (5.78%)	1 / 215 (0.47%)
occurrences (all)	34	42	1

Non-serious adverse events	VTd-DARA - Part 2	DVTd-OBS - Part 2	DVTd-DARA - Part 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	194 / 211 (91.94%)	198 / 229 (86.46%)	205 / 229 (89.52%)
Vascular disorders			
Hypertension			
subjects affected / exposed	18 / 211 (8.53%)	13 / 229 (5.68%)	10 / 229 (4.37%)
occurrences (all)	23	26	15
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	0 / 211 (0.00%)	0 / 229 (0.00%)	0 / 229 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	21 / 211 (9.95%)	29 / 229 (12.66%)	32 / 229 (13.97%)
occurrences (all)	22	37	37
Fatigue			
subjects affected / exposed	14 / 211 (6.64%)	17 / 229 (7.42%)	16 / 229 (6.99%)
occurrences (all)	17	21	20
Chills			
subjects affected / exposed	8 / 211 (3.79%)	1 / 229 (0.44%)	0 / 229 (0.00%)
occurrences (all)	8	1	0
Asthenia			
subjects affected / exposed	35 / 211 (16.59%)	26 / 229 (11.35%)	26 / 229 (11.35%)
occurrences (all)	43	28	31
Malaise			
subjects affected / exposed	6 / 211 (2.84%)	3 / 229 (1.31%)	2 / 229 (0.87%)
occurrences (all)	6	3	2
Oedema Peripheral			
subjects affected / exposed	9 / 211 (4.27%)	9 / 229 (3.93%)	13 / 229 (5.68%)
occurrences (all)	9	12	17
Pyrexia			
subjects affected / exposed	20 / 211 (9.48%)	17 / 229 (7.42%)	18 / 229 (7.86%)
occurrences (all)	26	21	25
Immune system disorders			

Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	30 / 211 (14.22%) 31	9 / 229 (3.93%) 9	30 / 229 (13.10%) 30
Respiratory, thoracic and mediastinal disorders			
Dyspnoea subjects affected / exposed occurrences (all)	20 / 211 (9.48%) 21	6 / 229 (2.62%) 6	9 / 229 (3.93%) 10
Cough subjects affected / exposed occurrences (all)	41 / 211 (19.43%) 54	23 / 229 (10.04%) 27	39 / 229 (17.03%) 54
Dyspnoea Exertional subjects affected / exposed occurrences (all)	3 / 211 (1.42%) 3	6 / 229 (2.62%) 6	5 / 229 (2.18%) 5
Rhinorrhoea subjects affected / exposed occurrences (all)	21 / 211 (9.95%) 22	10 / 229 (4.37%) 12	14 / 229 (6.11%) 15
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	8 / 211 (3.79%) 9	5 / 229 (2.18%) 5	9 / 229 (3.93%) 9
Anxiety subjects affected / exposed occurrences (all)	4 / 211 (1.90%) 4	6 / 229 (2.62%) 6	3 / 229 (1.31%) 3
Investigations			
Weight Decreased subjects affected / exposed occurrences (all)	3 / 211 (1.42%) 3	3 / 229 (1.31%) 3	4 / 229 (1.75%) 4
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	2 / 211 (0.95%) 2	4 / 229 (1.75%) 5	5 / 229 (2.18%) 5
Paraesthesia subjects affected / exposed occurrences (all)	21 / 211 (9.95%) 31	10 / 229 (4.37%) 10	15 / 229 (6.55%) 18
Headache			

subjects affected / exposed occurrences (all)	10 / 211 (4.74%) 11	8 / 229 (3.49%) 17	6 / 229 (2.62%) 6
Dysgeusia subjects affected / exposed occurrences (all)	1 / 211 (0.47%) 1	1 / 229 (0.44%) 1	1 / 229 (0.44%) 1
Peripheral Sensory Neuropathy subjects affected / exposed occurrences (all)	31 / 211 (14.69%) 42	27 / 229 (11.79%) 40	39 / 229 (17.03%) 53
Tremor subjects affected / exposed occurrences (all)	2 / 211 (0.95%) 2	0 / 229 (0.00%) 0	2 / 229 (0.87%) 2
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	8 / 211 (3.79%) 13	4 / 229 (1.75%) 9	2 / 229 (0.87%) 2
Febrile Neutropenia alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 211 (0.00%) 0	0 / 229 (0.00%) 0	1 / 229 (0.44%) 1
Neutropenia subjects affected / exposed occurrences (all)	7 / 211 (3.32%) 10	4 / 229 (1.75%) 4	5 / 229 (2.18%) 6
Lymphopenia subjects affected / exposed occurrences (all)	14 / 211 (6.64%) 35	12 / 229 (5.24%) 26	19 / 229 (8.30%) 32
Leukopenia subjects affected / exposed occurrences (all)	1 / 211 (0.47%) 1	1 / 229 (0.44%) 1	1 / 229 (0.44%) 1
Thrombocytopenia subjects affected / exposed occurrences (all)	7 / 211 (3.32%) 11	4 / 229 (1.75%) 6	10 / 229 (4.37%) 15
Ear and labyrinth disorders			
Vertigo subjects affected / exposed occurrences (all)	5 / 211 (2.37%) 5	5 / 229 (2.18%) 5	6 / 229 (2.62%) 6
Eye disorders			

Vision Blurred subjects affected / exposed occurrences (all)	1 / 211 (0.47%) 1	1 / 229 (0.44%) 1	2 / 229 (0.87%) 2
Gastrointestinal disorders			
Constipation subjects affected / exposed occurrences (all)	10 / 211 (4.74%) 11	6 / 229 (2.62%) 7	7 / 229 (3.06%) 7
Diarrhoea subjects affected / exposed occurrences (all)	33 / 211 (15.64%) 40	16 / 229 (6.99%) 20	25 / 229 (10.92%) 27
Abdominal Pain Upper subjects affected / exposed occurrences (all)	5 / 211 (2.37%) 5	5 / 229 (2.18%) 6	8 / 229 (3.49%) 11
Abdominal Pain subjects affected / exposed occurrences (all)	7 / 211 (3.32%) 8	4 / 229 (1.75%) 4	7 / 229 (3.06%) 8
Dry Mouth subjects affected / exposed occurrences (all)	0 / 211 (0.00%) 0	1 / 229 (0.44%) 1	1 / 229 (0.44%) 1
Nausea subjects affected / exposed occurrences (all)	33 / 211 (15.64%) 34	4 / 229 (1.75%) 4	10 / 229 (4.37%) 10
Stomatitis subjects affected / exposed occurrences (all)	0 / 211 (0.00%) 0	2 / 229 (0.87%) 2	2 / 229 (0.87%) 2
Vomiting subjects affected / exposed occurrences (all)	31 / 211 (14.69%) 33	3 / 229 (1.31%) 3	8 / 229 (3.49%) 9
Skin and subcutaneous tissue disorders			
Eczema subjects affected / exposed occurrences (all)	11 / 211 (5.21%) 11	4 / 229 (1.75%) 5	7 / 229 (3.06%) 8
Erythema subjects affected / exposed occurrences (all)	14 / 211 (6.64%) 14	1 / 229 (0.44%) 1	7 / 229 (3.06%) 8
Pruritus			

subjects affected / exposed occurrences (all)	17 / 211 (8.06%) 17	6 / 229 (2.62%) 8	7 / 229 (3.06%) 7
Rash subjects affected / exposed occurrences (all)	17 / 211 (8.06%) 18	7 / 229 (3.06%) 7	8 / 229 (3.49%) 10
Dry Skin subjects affected / exposed occurrences (all)	4 / 211 (1.90%) 4	6 / 229 (2.62%) 6	5 / 229 (2.18%) 6
Musculoskeletal and connective tissue disorders			
Back Pain subjects affected / exposed occurrences (all)	19 / 211 (9.00%) 22	31 / 229 (13.54%) 37	26 / 229 (11.35%) 29
Arthralgia subjects affected / exposed occurrences (all)	20 / 211 (9.48%) 24	27 / 229 (11.79%) 32	31 / 229 (13.54%) 33
Bone Pain subjects affected / exposed occurrences (all)	24 / 211 (11.37%) 29	14 / 229 (6.11%) 16	19 / 229 (8.30%) 21
Musculoskeletal Pain subjects affected / exposed occurrences (all)	8 / 211 (3.79%) 9	16 / 229 (6.99%) 16	11 / 229 (4.80%) 11
Myalgia subjects affected / exposed occurrences (all)	11 / 211 (5.21%) 14	8 / 229 (3.49%) 8	20 / 229 (8.73%) 26
Pain in Extremity subjects affected / exposed occurrences (all)	9 / 211 (4.27%) 10	11 / 229 (4.80%) 11	17 / 229 (7.42%) 18
Muscle Spasms subjects affected / exposed occurrences (all)	15 / 211 (7.11%) 19	3 / 229 (1.31%) 3	9 / 229 (3.93%) 11
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	37 / 211 (17.54%) 54	29 / 229 (12.66%) 36	39 / 229 (17.03%) 56
Herpes Zoster			

subjects affected / exposed occurrences (all)	14 / 211 (6.64%) 14	39 / 229 (17.03%) 40	17 / 229 (7.42%) 18
Pneumonia subjects affected / exposed occurrences (all)	7 / 211 (3.32%) 8	8 / 229 (3.49%) 8	12 / 229 (5.24%) 15
Bronchitis subjects affected / exposed occurrences (all)	77 / 211 (36.49%) 126	63 / 229 (27.51%) 102	93 / 229 (40.61%) 151
Gastroenteritis subjects affected / exposed occurrences (all)	16 / 211 (7.58%) 16	16 / 229 (6.99%) 21	22 / 229 (9.61%) 23
Rhinitis subjects affected / exposed occurrences (all)	19 / 211 (9.00%) 24	13 / 229 (5.68%) 14	20 / 229 (8.73%) 26
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	29 / 211 (13.74%) 34	27 / 229 (11.79%) 43	35 / 229 (15.28%) 50
Sinusitis subjects affected / exposed occurrences (all)	18 / 211 (8.53%) 21	9 / 229 (3.93%) 10	13 / 229 (5.68%) 21
Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	1 / 211 (0.47%) 1	3 / 229 (1.31%) 3	6 / 229 (2.62%) 6
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 211 (0.47%) 1	2 / 229 (0.87%) 5	1 / 229 (0.44%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 August 2015	Amendment 1 <ul style="list-style-type: none">- Inclusion/exclusion criteria updated to include specific CRAB criteria (CRAB=calcium elevation, renal insufficiency, anemia and bone abnormalities), include free light chain for quantification of immunoglobulin D (IgD), and allow for controlled arrhythmias and vertebroplasty- Other changes including alignment with daratumumab standard protocol wording, updated missing text and adding further text clarification to allow better understanding of the protocol design and requirements
21 March 2016	Amendment 2 <ul style="list-style-type: none">- Exclusion criteria updated to exclude solitary plasmacytoma- Other changes to ensure better differentiation between the induction/ASCT/consolidation and maintenance phases of the study and the respective Time & Events schedule to allow better understanding of the assessments. In addition, further updates to align with the International Myeloma Working Group (IMWG) publications and recommendations
05 July 2019	Amendment 3 <ul style="list-style-type: none">- Precisions and clarifications added regarding End of Treatment (EOT) Visit and Follow-Up (FU) visits (Pre-Progressive Disease/Progressive Disease/Survival) procedures- Addition of Infusion Related-Reaction (IRR) definition- Update of safety information in line with Investigator Brochure (IB) update (IB15 and its addendum 1)- Addition of recommendations already communicated to sites for Part I for harmonization purposes- Clarification regarding procedure in case of suspected daratumumab interference on Serum M-Protein ElectroPhoresis (SPEP) and immunofixation (IFE)- Clarification for recording the response to treatment- Clarification for recording any new malignancy event as an Serious Adverse Event (SAE)- Clarifications regarding SAE declaration circuit- Changes in formulation/structure for accuracy and better understanding of protocol procedures- New Minimal Residual Disease (MRD) assessments during Pre-Progression Follow-up- Changes in bisphosphonate therapy recommendations- Change of IFM Director
14 January 2021	Amendment 4 <ul style="list-style-type: none">- Modification of Pre-PD FU visit frequency (PD=Progressive Disease;FU=Follow-Up)- Independent Data Monitoring Committee (IDMC) meetings not needed after the unblinding of the data- The interim analysis for Progression-Free Survival (PFS) met the predefined boundary and turned into the final analysis of Part 2 for PFS. Change in monitoring strategy: risk-based approach with remote quality control of data/risk-based monitoring- Addition of analyses of screening aliquots using Next Generation Sequencing (NGS) methodology

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/31171419>

<http://www.ncbi.nlm.nih.gov/pubmed/34529931>

<http://www.ncbi.nlm.nih.gov/pubmed/38889735>