Clinical trial results:
A Phase 1/2 Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 701 Monotherapy, or in Combination With Pomalidomide, With and Without Dexamethasone in Subjects With Relapsed or Refractory Multiple Myeloma (ParadigMM-1B)

Summary

EudraCT number	2017-001997-41
Trial protocol	DE NL BE
Global end of trial date	30 June 2023

Results information

Result version number	v1 (current)
This version publication date	14 June 2024
First version publication date	14 June 2024

Trial information

Trial identification

Sponsor protocol code	20170122

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03287908
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States,
Public contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 June 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 June 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to evaluate the safety and tolerability of AMG 701 in participants with relapsed/refractory multiple myeloma (RRMM) to determine the maximum tolerated dose and/or recommended phase 2 dose (RP2D).

Protection of trial subjects:

The study was conducted in accordance with the protocol and with the consensus of ethical principles derived from international guidelines including the Declaration of Helsinki and Council for International Organizations of Medical Sciences International Ethical Guidelines, applicable International Conference on Harmonisation (ICH) Good Clinical Practice Guidelines, and applicable ICH laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 November 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 24
Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Germany: 9
Country: Number of subjects enrolled	Japan: 8
Country: Number of subjects enrolled	Netherlands: 20
Country: Number of subjects enrolled	United States: 107
Worldwide total number of subjects	174
EEA total number of subjects	29

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)	88
From 65 to 84 years	86
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at 28 study centers in 6 countries and participated from November 2017 to June 2023.

Pre-assignment

Screening details:

Participants were enrolled into sequential dose-exploration and dose-confirmation cohorts to receive AMG 701 monotherapy with different dose step scenarios. Doses ranged from Dose A to Dose O (lowest to highest).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: AMG 701 Dose A

Arm description:

AMG 701 Dose A was administered as a weekly intravenous (IV) infusion in a 4-week cycle with no step dosing.

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 2: AMG 701 Dose B

Arm description:

AMG 701 Dose B was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 3: AMG 701 Dose C

Arm description:

AMG 701 Dose C was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Arm type	Experimental

Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 4: AMG 701 Dose D

Arm description:

AMG 701 Dose D was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 5: AMG 701 Dose E

Arm description:

AMG 701 Dose E was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 6: AMG 701 Dose F

Arm description:

AMG 701 Dose F was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 7: AMG 701 Dose H

Arm description:

AMG 701 Dose H was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 8: AMG 701 Dose F/Dose G

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on Cycle (C) 1 Day (D) 1 and AMG 701 Dose G weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 9: AMG 701 Dose F/Dose H

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose H weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 9 extension (ext): AMG 701 Dose F/Dose H

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose H weekly from C1D5 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 10: AMG 701 Dose F/Dose I

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose I weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 10 ext: AMG 701 Dose F/Dose I

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose I weekly from C1D5 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 11: AMG 701 Dose F/Dose J

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose J weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 11 ext: AMG 701 Dose F/Dose J

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose J weekly from C1D5 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 12: AMG 701 Dose F/Dose L

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose L weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 12 ext: AMG 701 Dose F/Dose L

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose L weekly from C1D3 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 13: AMG 701 Dose F/Dose M

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose M weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 13 ext: AMG 701 Dose F/Dose M

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose M weekly from C1D3 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 14: AMG 701 Dose F/Dose N

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose N weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 14 ext: AMG 701 Dose F/Dose N

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose N weekly from C1D3 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 15: AMG 701 Dose F/Dose O

Arm description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose O weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N

Arm description:

AMG 701 Dose G/day was administered as an extended IV (eIV) infusion over 7 days and participants received AMG 701 Dose N weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 14A: AMG 701 Dose F/Dose M/Dose N

Arm description:

AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose M on C1D3, and AMG 701 Dose N weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 15A: AMG 701 Dose F/Dose M/Dose O

Arm description:

AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose M on C1D3, and AMG 701 Dose O weekly from C1D8 (4-week cycle).

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O

Arm description:

AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose K on C1D3, and AMG 701 Dose O weekly from C1D8 (4-week cycle).
Group 1 included participants who did not receive a prior B-cell maturation antigen (BCMA) targeting therapy.

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O

Arm description:

AMG 701 was administered as an IV infusion with three-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose J on C1D3, AMG 701 Dose M on C1D5, and AMG 701 Dose O weekly from C1D8 (4-week cycle).
Group 1 included participants who did not receive a prior BCMA targeting therapy.

Arm type	Experimental
Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Arm title	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O

Arm description:

AMG 701 was administered as an IV infusion with three-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose J on C1D3, AMG 701 Dose M on C1D5, and AMG 701 Dose O weekly from C1D8 (4-week cycle).
Group 2 included participants who had relapsed or were intolerant to prior BCMA targeting therapy.

Arm type	Experimental

Investigational medicinal product name	AMG 701
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV doses of AMG 701.

Number of subjects in period 1	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C
Started	1	1	1
Safety Analysis Set	1	1	1
Completed	0	0	0
Not completed	1	1	1
Consent withdrawn by subject	1	-	-
Death	-	1	1
Sponsor decision	-	-	-

Number of subjects in period 1	Cohort 4: AMG 701 Dose D	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F
Started	3	4	4
Safety Analysis Set	3	4	4
Completed	0	1	0
Not completed	3	3	4
Consent withdrawn by subject	-	1	-
Death	3	2	2
Sponsor decision	-	-	2

Number of subjects in period 1	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G	Cohort 9: AMG 701 Dose F/Dose H
Started	1	4	5
Safety Analysis Set	1	4	5
Completed	0	0	0
Not completed	1	4	5
Consent withdrawn by subject	-	-	1
Death	1	4	4
Sponsor decision	-	-	-

Number of subjects in period 1	Cohort 9 extension (ext): AMG 701 Dose F/Dose H	Cohort 10: AMG 701 Dose F/Dose I	Cohort 10 ext: AMG 701 Dose F/Dose I
Started	3	8	3
Safety Analysis Set	3	8	3
Completed	0	0	0
Not completed	3	8	3
Consent withdrawn by subject	-	-	-

Death	2	7	1
Sponsor decision	1	1	2

Number of subjects in period 1	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L
Started	4	3	6
Safety Analysis Set	4	3	5
Completed	0	0	0
Not completed	4	3	6
Consent withdrawn by subject	-	-	2
Death	2	2	1
Sponsor decision	2	1	3

Number of subjects in period 1	Cohort 12 ext: AMG 701 Dose F/Dose L	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M
Started	5	4	6
Safety Analysis Set	5	4	6
Completed	0	0	0
Not completed	5	4	6
Consent withdrawn by subject	1	1	-
Death	2	3	6
Sponsor decision	2	-	-

Number of subjects in period 1	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N	Cohort 15: AMG 701 Dose F/Dose O
Started	5	9	4
Safety Analysis Set	5	9	4
Completed	0	0	0
Not completed	5	9	4
Consent withdrawn by subject	-	2	1
Death	4	4	2
Sponsor decision	1	3	1

Number of subjects in period 1	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Started	4	4	8
Safety Analysis Set	4	4	8
Completed	0	0	0
Not completed	4	4	8
Consent withdrawn by subject	-	-	-
Death	3	2	7
Sponsor decision	1	2	1

Number of subjects in period 1	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O
Started	32	32	10

Safety Analysis Set	32	31	10
Completed	0	0	0
Not completed	32	32	10
Consent withdrawn by subject	5	3	3
Death	11	8	4
Sponsor decision	16	21	3

Baseline characteristics

Reporting groups

Reporting group title	Cohort 1: AMG 701 Dose A
Reporting group description:	
AMG 701 Dose A was administered as a weekly intravenous (IV) infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 2: AMG 701 Dose B
Reporting group description:	
AMG 701 Dose B was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 3: AMG 701 Dose C
Reporting group description:	
AMG 701 Dose C was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 4: AMG 701 Dose D
Reporting group description:	
AMG 701 Dose D was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 5: AMG 701 Dose E
Reporting group description:	
AMG 701 Dose E was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 6: AMG 701 Dose F
Reporting group description:	
AMG 701 Dose F was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 7: AMG 701 Dose H
Reporting group description:	
AMG 701 Dose H was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 8: AMG 701 Dose F/Dose G
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on Cycle (C) 1 Day (D) 1 and AMG 701 Dose G weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 9: AMG 701 Dose F/Dose H
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose H weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 9 extension (ext): AMG 701 Dose F/Dose H
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose H weekly from C1D5 (4-week cycle).	
Reporting group title	Cohort 10: AMG 701 Dose F/Dose I
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose I weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 10 ext: AMG 701 Dose F/Dose I
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose I weekly from C1D5 (4-week cycle).	
Reporting group title	Cohort 11: AMG 701 Dose F/Dose J
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose J weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 11 ext: AMG 701 Dose F/Dose J
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose J weekly from C1D5 (4-week cycle).	

Reporting group title	Cohort 12: AMG 701 Dose F/Dose L

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose L weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 12 ext: AMG 701 Dose F/Dose L

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose L weekly from C1D3 (4-week cycle).

Reporting group title	Cohort 13: AMG 701 Dose F/Dose M

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose M weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 13 ext: AMG 701 Dose F/Dose M

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose M weekly from C1D3 (4-week cycle).

Reporting group title	Cohort 14: AMG 701 Dose F/Dose N

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose N weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 14 ext: AMG 701 Dose F/Dose N

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose N weekly from C1D3 (4-week cycle).

Reporting group title	Cohort 15: AMG 701 Dose F/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose O weekly from C1D8 (4-week cycle).

Reporting group title	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N

Reporting group description:

AMG 701 Dose G/day was administered as an extended IV (eIV) infusion over 7 days and participants received AMG 701 Dose N weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 14A: AMG 701 Dose F/Dose M/Dose N

Reporting group description:

AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose M on C1D3, and AMG 701 Dose N weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 15A: AMG 701 Dose F/Dose M/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose M on C1D3, and AMG 701 Dose O weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose K on C1D3, and AMG 701 Dose O weekly from C1D8 (4-week cycle).
Group 1 included participants who did not receive a prior B-cell maturation antigen (BCMA) targeting therapy.

Reporting group title	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with three-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose J on C1D3, AMG 701 Dose M on C1D5, and AMG 701 Dose O weekly from C1D8 (4-week cycle).
Group 1 included participants who did not receive a prior BCMA targeting therapy.

Reporting group title	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with three-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose J on C1D3, AMG 701 Dose M on C1D5, and AMG 701 Dose O weekly from C1D8 (4-week cycle).
Group 2 included participants who had relapsed or were intolerant to prior BCMA targeting therapy.

Reporting group values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C
Number of subjects	1	1	1
Age Categorical Units: Participants			
0-17 years	0	0	0
18-64 years	1	1	1
65-74 years	0	0	0
75-84 years	0	0	0
≥ 85 years	0	0	0
Age Continuous Units: years			
median	55.0	63.0	48.0
full range (min-max)	55 to 55	63 to 63	48 to 48
Gender Categorical Units: Participants			
Female	0	1	1
Male	1	0	0
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black (or African American)	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	0	1	1
Multiple	0	0	0
Other	1	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	0	1	1

Reporting group values	Cohort 4: AMG 701 Dose D	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F
Number of subjects	3	4	4
Age Categorical Units: Participants			
0-17 years	0	0	0
18-64 years	2	3	2
65-74 years	1	1	1
75-84 years	0	0	1
≥ 85 years	0	0	0
Age Continuous Units: years			
median	61.0	55.0	64.5
full range (min-max)	58 to 71	50 to 65	58 to 81
Gender Categorical Units: Participants			
Female	3	3	2

Male	0	1	2

Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black (or African American)	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	3	4	3
Multiple	0	0	0
Other	0	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	4	4

Reporting group values	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G	Cohort 9: AMG 701 Dose F/Dose H
Number of subjects	1	4	5
Age Categorical Units: Participants			
0-17 years	0	0	0
18-64 years	0	2	5
65-74 years	1	1	0
75-84 years	0	1	0
≥ 85 years	0	0	0
Age Continuous Units: years			
median	69.0	68.5	53.0
full range (min-max)	69 to 69	47 to 83	49 to 59
Gender Categorical Units: Participants			
Female	0	4	1
Male	1	0	4
Race Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	0	0	0
Black (or African American)	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	1	4	4
Multiple	0	0	0
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	1	3	5

Reporting group values	Cohort 9 extension (ext): AMG 701	Cohort 10: AMG 701 Dose F/Dose I	Cohort 10 ext: AMG 701 Dose F/Dose I

	Dose F/Dose H		
Number of subjects	3	8	3
Age Categorical Units: Participants			
0-17 years	0	0	0
18-64 years	1	5	0
65-74 years	2	2	2
75-84 years	0	1	1
≥ 85 years	0	0	0
Age Continuous Units: years			
median	71.0	62.5	73.0
full range (min-max)	49 to 72	55 to 76	69 to 77
Gender Categorical Units: Participants			
Female	2	3	2
Male	1	5	1
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black (or African American)	0	3	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	3	4	2
Multiple	0	0	0
Other	0	1	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	2	0
Not Hispanic or Latino	3	6	3

Reporting group values	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L
Number of subjects	4	3	6
Age Categorical Units: Participants			
0-17 years	0	0	0
18-64 years	1	1	5
65-74 years	2	2	1
75-84 years	1	0	0
≥ 85 years	0	0	0
Age Continuous Units: years			
median	70.0	65.0	53.5
full range (min-max)	53 to 78	63 to 70	48 to 67
Gender Categorical Units: Participants			
Female	1	1	3
Male	3	2	3

Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Black (or African American)	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
White	3	2	4
Multiple	0	0	0
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	4	3	6

Reporting group values	Cohort 12 ext: AMG 701 Dose F/Dose L	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M
Number of subjects	5	4	6
Age Categorical Units: Participants			
0-17 years	0	0	0
18-64 years	2	2	1
65-74 years	3	2	4
75-84 years	0	0	1
≥ 85 years	0	0	0
Age Continuous Units: years			
median	70.0	62.0	68.0
full range (min-max)	34 to 74	55 to 71	53 to 76
Gender Categorical Units: Participants			
Female	3	1	1
Male	2	3	5
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black (or African American)	1	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	4	3	3
Multiple	0	0	0
Other	0	0	2
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	2
Not Hispanic or Latino	5	4	4

Reporting group values	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N	Cohort 15: AMG 701 Dose F/Dose O
Number of subjects	5	9	4

Age Categorical Units: Participants			
0-17 years	0	0	0
18-64 years	4	3	1
65-74 years	1	4	2
75-84 years	0	2	1
≥ 85 years	0	0	0
Age Continuous Units: years			
median	57.0	67.0	72.0
full range (min-max)	46 to 72	55 to 79	56 to 82
Gender Categorical Units: Participants			
Female	1	5	2
Male	4	4	2
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	1
Black (or African American)	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	5	8	2
Multiple	0	0	0
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	5	9	4

Reporting group values	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Number of subjects	4	4	8
Age Categorical Units: Participants			
0-17 years	0	0	0
18-64 years	1	3	3
65-74 years	2	1	4
75-84 years	1	0	1
≥ 85 years	0	0	0
Age Continuous Units: years			
median	70.0	50.5	67.0
full range (min-max)	61 to 77	41 to 66	60 to 75
Gender Categorical Units: Participants			
Female	1	1	5
Male	3	3	3
Race Units: Subjects			
American Indian or Alaska Native	0	0	0

Asian	0	0	0
Black (or African American)	1	2	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	2	2	7
Multiple	0	0	0
Other	1	0	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	3	4	8

Reporting group values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O
Number of subjects	32	32	10
Age Categorical			
Units: Participants			
0-17 years	0	0	0
18-64 years	16	14	8
65-74 years	11	18	2
75-84 years	5	0	0
≥ 85 years	0	0	0
Age Continuous			
Units: years			
median	65.0	65.0	62.0
full range (min-max)	44 to 82	51 to 74	52 to 70
Gender Categorical			
Units: Participants			
Female	17	14	6
Male	15	18	4
Race			
Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	3	2	1
Black (or African American)	1	2	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	25	25	7
Multiple	0	0	1
Other	3	2	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	2	0
Not Hispanic or Latino	32	30	10

Reporting group values	Total		
Number of subjects	174		
Age Categorical			
Units: Participants			
0-17 years	0		
18-64 years	88		

65-74 years	70		
75-84 years	16		
≥ 85 years	0		
Age Continuous			
Units: years			
median			
full range (min-max)	-		
Gender Categorical			
Units: Participants			
Female	84		
Male	90		
Race			
Units: Subjects			
American Indian or Alaska Native	2		
Asian	10		
Black (or African American)	18		
Native Hawaiian or Other Pacific Islander	0		
White	132		
Multiple	1		
Other	11		
Ethnicity			
Units: Subjects			
Hispanic or Latino	9		
Not Hispanic or Latino	165		

End points

End points reporting groups

Reporting group title	Cohort 1: AMG 701 Dose A
Reporting group description:	
AMG 701 Dose A was administered as a weekly intravenous (IV) infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 2: AMG 701 Dose B
Reporting group description:	
AMG 701 Dose B was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 3: AMG 701 Dose C
Reporting group description:	
AMG 701 Dose C was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 4: AMG 701 Dose D
Reporting group description:	
AMG 701 Dose D was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 5: AMG 701 Dose E
Reporting group description:	
AMG 701 Dose E was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 6: AMG 701 Dose F
Reporting group description:	
AMG 701 Dose F was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 7: AMG 701 Dose H
Reporting group description:	
AMG 701 Dose H was administered as a weekly IV infusion in a 4-week cycle with no step dosing.	
Reporting group title	Cohort 8: AMG 701 Dose F/Dose G
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on Cycle (C) 1 Day (D) 1 and AMG 701 Dose G weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 9: AMG 701 Dose F/Dose H
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose H weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 9 extension (ext): AMG 701 Dose F/Dose H
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose H weekly from C1D5 (4-week cycle).	
Reporting group title	Cohort 10: AMG 701 Dose F/Dose I
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose I weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 10 ext: AMG 701 Dose F/Dose I
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose I weekly from C1D5 (4-week cycle).	
Reporting group title	Cohort 11: AMG 701 Dose F/Dose J
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose J weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 11 ext: AMG 701 Dose F/Dose J
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose J weekly from C1D5 (4-week cycle).	

Reporting group title	Cohort 12: AMG 701 Dose F/Dose L
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose L weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 12 ext: AMG 701 Dose F/Dose L
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose L weekly from C1D3 (4-week cycle).	
Reporting group title	Cohort 13: AMG 701 Dose F/Dose M
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose M weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 13 ext: AMG 701 Dose F/Dose M
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose M weekly from C1D3 (4-week cycle).	
Reporting group title	Cohort 14: AMG 701 Dose F/Dose N
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose N weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 14 ext: AMG 701 Dose F/Dose N
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose N weekly from C1D3 (4-week cycle).	
Reporting group title	Cohort 15: AMG 701 Dose F/Dose O
Reporting group description:	
AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose O weekly from C1D8 (4-week cycle).	
Reporting group title	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N
Reporting group description:	
AMG 701 Dose G/day was administered as an extended IV (eIV) infusion over 7 days and participants received AMG 701 Dose N weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 14A: AMG 701 Dose F/Dose M/Dose N
Reporting group description:	
AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose M on C1D3, and AMG 701 Dose N weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Reporting group description:	
AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose M on C1D3, and AMG 701 Dose O weekly from C1D8 (4-week cycle).	
Reporting group title	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O
Reporting group description:	
AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose K on C1D3, and AMG 701 Dose O weekly from C1D8 (4-week cycle). Group 1 included participants who did not receive a prior B-cell maturation antigen (BCMA) targeting therapy.	
Reporting group title	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O
Reporting group description:	
AMG 701 was administered as an IV infusion with three-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose J on C1D3, AMG 701 Dose M on C1D5, and AMG 701 Dose O weekly from C1D8 (4-week cycle). Group 1 included participants who did not receive a prior BCMA targeting therapy.	
Reporting group title	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O
Reporting group description:	
AMG 701 was administered as an IV infusion with three-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose J on C1D3, AMG 701 Dose M on C1D5, and AMG 701 Dose O weekly from C1D8 (4-week cycle). Group 2 included participants who had relapsed or were intolerant to prior BCMA targeting therapy.	

Subject analysis set title	Cohort 9 and Cohort 9 ext Combined
Subject analysis set type	Per protocol

Subject analysis set description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose H weekly from C1D5 (Cohort 9 ext) or C1D8 (Cohort 9) (4-week cycle).

Subject analysis set title	Cohort 10 and Cohort 10 ext Combined
Subject analysis set type	Per protocol

Subject analysis set description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose I weekly from C1D5 (Cohort 10 ext) or C1D8 (Cohort 10) (4-week cycle).

Subject analysis set title	Cohort 11 and Cohort 11 ext Combined
Subject analysis set type	Per protocol

Subject analysis set description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose J weekly from C1D5 (Cohort 11 ext) or C1D8 (Cohort 11) (4-week cycle).

Subject analysis set title	Cohort 12 and Cohort 12 ext Combined
Subject analysis set type	Per protocol

Subject analysis set description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose L weekly from C1D3 (Cohort 12 ext) or C1D8 (Cohort 12) (4-week cycle).

Subject analysis set title	Cohort 13 and Cohort 13 ext Combined
Subject analysis set type	Per protocol

Subject analysis set description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose M weekly from C1D3 (Cohort 13 ext) or C1D8 (Cohort 13) (4-week cycle).

Subject analysis set title	Cohort 14 and Cohort 14 ext Combined
Subject analysis set type	Per protocol

Subject analysis set description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose N weekly from C1D3 (Cohort 14 ext) or C1D8 (Cohort 14) (4-week cycle).

Primary: Number of Participants who Experienced a Dose Limiting Toxicity (DLT)

End point title	Number of Participants who Experienced a Dose Limiting Toxicity (DLT)[1]

End point description:

A DLT was any of the following during the DLT window, assessed by Common Terminology Criteria for Adverse Events v4.0:
- Non-hematological adverse event (AE) ≥ grade 3, except: infection responding to treatment ≤ 48 hours; grade 3 fatigue/asthenia; headache resolving ≤ 72 hours ≤ grade 2; insomnia; grade 3 fever, nausea, vomiting or diarrhea resolving ≤ 72 hours; grade 3 laboratory parameters not clinically relevant and improving to grade ≤ 2 ≤ 72 hours or 7 days for parameters with long half-lives; grade 3/4 elevated lipase or amylase with no criteria suggestive of pancreatitis and improving to grade ≤ 2 ≤ 7 days; meeting criteria for Hy's Law. - Hematologic DLTs: febrile neutropenia grade 4 or grade 3 unless responding to treatment ≤ 48 hours; neutropenia grade 3 > 10 days or grade 4 > 5 days; thrombocytopenia grade 4 > 7 days or with hemorrhage or requiring transfusion or grade 3 with grade 3 hemorrhage; anemia grade 3 with symptoms or grade 4 without multiple myeloma.

End point type	Primary

End point timeframe:

Day 1 up to 28 days (28 days)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No comparative statistical analysis was planned for this endpoint.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[2]	1[3]	1[4]	3[5]
Units: participants	0	0	0	0

Notes:

[2] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[3] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[4] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[5] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[6]	3[7]	1[8]	3[9]
Units: participants	0	0	1	0

Notes:

[6] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[7] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[8] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[9] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.

End point values	Cohort 9: AMG 701 Dose F/Dose H	Cohort 9 extension (ext): AMG 701 Dose F/Dose H	Cohort 10: AMG 701 Dose F/Dose I	Cohort 10 ext: AMG 701 Dose F/Dose I
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[10]	3[11]	7[12]	3[13]
Units: participants	0	0	1	1

Notes:

[10] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[11] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[12] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[13] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.

End point values	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L	Cohort 12 ext: AMG 701 Dose F/Dose L
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[14]	2[15]	5[16]	5[17]
Units: participants	0	0	2	0

Notes:

[14] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[15] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[16] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT

window.

[17] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.

End point values	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[18]	6[19]	4[20]	9[21]
Units: participants	1	1	0	2

Notes:

[18] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[19] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[20] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[21] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[22]	3[23]	3[24]	8[25]
Units: participants	1	1	0	1

Notes:

[22] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[23] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[24] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[25] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10[26]	0[27]	9[28]	
Units: participants	0		0	

Notes:

[26] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[27] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.
[28] - DLT analysis set included DLT-evaluable participants who experienced a DLT during the DLT window.

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Participants with Treatment-emergent Adverse Events (TEAEs)[29]

End point description:

An AE was defined as any untoward medical occurrence in a clinical trial participant. A TEAE was an AE that started on or after the first dose of investigational product (IP) (AMG 701) up to 33 days after the last dose of the IP or the end of study, whichever was earlier. Any clinically significant changes in vital signs, physical examinations, electrocardiograms, and clinical laboratory tests were included as TEAEs.

A treatment-related AE was any TEAE that per investigator review had a reasonable possibility of being caused by AMG 701.

The safety analysis set included all participants who were enrolled and received at least one dose of AMG 701.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 up to 30 days after the last dose of AMG 701; median duration was 4.1 months

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No comparative statistical analysis was planned for this endpoint.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	1	3
Units: Participants				
Any TEAE	1	1	1	3
Any treatment-related TEAE	0	0	1	3

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	1	4
Units: Participants				
Any TEAE	4	4	1	4
Any treatment-related TEAE	4	4	1	3

End point values	Cohort 9: AMG 701 Dose F/Dose H	Cohort 9 extension (ext): AMG 701 Dose F/Dose H	Cohort 10: AMG 701 Dose F/Dose I	Cohort 10 ext: AMG 701 Dose F/Dose I
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	8	3
Units: Participants				
Any TEAE	5	3	8	3
Any treatment-related TEAE	4	2	7	3

End point values	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L	Cohort 12 ext: AMG 701 Dose F/Dose L

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	5
Units: Participants				
Any TEAE	4	3	5	5
Any treatment-related TEAE	4	2	5	5

End point values	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	5	9
Units: Participants				
Any TEAE	4	6	5	9
Any treatment-related TEAE	4	6	5	9

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	8
Units: Participants				
Any TEAE	4	4	4	8
Any treatment-related TEAE	4	4	4	8

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	31	10	
Units: Participants				
Any TEAE	32	31	10	
Any treatment-related TEAE	32	31	10	

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Serum Concentration of AMG 701 (Cmax) of AMG 701

End point title	Maximum Serum Concentration of AMG 701 (Cmax) of AMG 701[30]

End point description:

The pharmacokinetic (PK) parameters were determined using non-compartmental approaches and considering the time-concentration profile over the complete sampling interval.
The PK analysis set contained participants who had received at least one dose of AMG 701 and had at least one PK sample collected. These participants were evaluated for PK analysis unless the number of data points required for analysis was not enough, or significant protocol deviations had affected the data, or if key dosing or sampling information was missing. Data is presented for free serum AMG 701. 99999 indicates the value was not reported due to N = 0, or N = 1 and the standard deviation was not calculated.

End point type	Secondary

End point timeframe:

Cohorts 1 and 2: C1D1, C1D8, and C1D15;
Cohort 7: C1D1;
Cohorts 8 and 15: C1D1, C1D15, and C1D22;
All other cohorts: C1D1, C1D8, C1D15, and C1D22 (sampling pre-dose up to 120 hours post-dose; up to 144 hours post C1D8 for Cohort 16 only)

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data for all cohorts are included in the endpoint, using a combination of reporting arms and subject analysis sets.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[31]	1[32]	1[33]	3[34]
Units: ng/mL				
arithmetic mean (standard deviation)				
C1D1	0.203 (± 99999)	0.072 (± 99999)	1.14 (± 99999)	0.384 (± 0.0558)
C1D8	0.083 (± 99999)	0.082 (± 99999)	2.69 (± 99999)	0.381 (± 0.0237)
C1D15	0.322 (± 99999)	0.404 (± 99999)	1.98 (± 99999)	0.329 (± 0.065)
C1D22	99999 (± 99999)	99999 (± 99999)	2.22 (± 99999)	0.341 (± 0.116)

Notes:

[31] - (N=1, 1, 1, 0)

[32] - (N=1, 1, 1, 0)

[33] - (N=1, 1, 1, 1)

[34] - (N=3, 3, 3, 3)

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[35]	4[36]	1[37]	4[38]
Units: ng/mL				
arithmetic mean (standard deviation)				
C1D1	2.25 (± 1.63)	39.1 (± 63.5)	1.1 (± 99999)	40.5 (± 68.6)
C1D8	2.52 (± 1.92)	55.6 (± 88.7)	99999 (± 99999)	99999 (± 99999)
C1D15	2.22 (± 2.07)	68.8 (± 109)	99999 (± 99999)	105 (± 143)
C1D22	2.45 (± 2.71)	82.8 (± 132)	99999 (± 99999)	105 (± 147)

Notes:

[35] - (N=4, 4, 3, 3)

[36] - (N=4, 3, 3, 3)

[37] - (N=1, 0, 0, 0)

[38] - (N=4, 0, 3, 3)

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[39]	3[40]	4[41]	8[42]
Units: ng/mL				
arithmetic mean (standard deviation)				
C1D1	14.7 (± 9.55)	15.7 (± 12.5)	1040 (± 926)	1250 (± 1650)
C1D8	99999 (± 99999)	769 (± 99999)	2310 (± 1850)	1980 (± 1650)
C1D15	2750 (± 2070)	99999 (± 99999)	2360 (± 1960)	2680 (± 1420)
C1D22	2880 (± 1820)	99999 (± 99999)	2220 (± 1880)	3100 (± 1410)

Notes:

[39] - (N=4, 0, 3, 4)

[40] - (N=3, 1, 0, 0)

[41] - (N=4, 3, 3, 3)

[42] - (N=8, 4, 7, 7)

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 9 and Cohort 9 ext Combined
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12[43]	20[44]	9[45]	8[46]
Units: ng/mL				
arithmetic mean (standard deviation)				
C1D1	490 (± 693)	779 (± 784)	661 (± 1100)	9.63 (± 12.8)
C1D8	2170 (± 1810)	2810 (± 1360)	1980 (± 1780)	66 (± 126)
C1D15	2740 (± 1230)	3040 (± 1320)	1470 (± 1700)	84 (± 153)
C1D22	2900 (± 1610)	3130 (± 1220)	195 (± 86.3)	106 (± 246)

Notes:

[43] - (N=12, 8, 10, 8)

[44] - (N=20, 13, 14, 14)

[45] - (N=9, 5, 4, 2)

[46] - (N=8, 8, 7, 8)

End point values	Cohort 10 and Cohort 10 ext Combined	Cohort 11 and Cohort 11 ext Combined	Cohort 12 and Cohort 12 ext Combined	Cohort 13 and Cohort 13 ext Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11[47]	7[48]	10[49]	10[50]
Units: ng/mL				
arithmetic mean (standard deviation)				
C1D1	7.54 (± 8.27)	35.9 (± 82.4)	462 (± 669)	476 (± 1080)
C1D8	129 (± 198)	223 (± 341)	1110 (± 950)	213 (± 410)
C1D15	112 (± 177)	293 (± 540)	1440 (± 1130)	373 (± 506)

C1D22	81.3 (± 169)	402 (± 456)	1380 (± 1260)	806 (± 1130)

Notes:

[47] - (N=11, 11, 9, 8)

[48] - (N=6, 7, 5, 5)

[49] - (N=10, 8, 8, 6)

[50] - (N=10, 8, 9, 9)

End point values	Cohort 14 and Cohort 14 ext Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	14[51]			
Units: ng/mL				
arithmetic mean (standard deviation)				
C1D1	1510 (± 1580)			
C1D8	2320 (± 1560)			
C1D15	2490 (± 1500)			
C1D22	2320 (± 1600)			

Notes:

[51] - (N=14, 12, 13, 11)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Cmax (Tmax) of AMG 701

End point title	Time to Cmax (Tmax) of AMG 701[52]

End point description:

The PK parameters were determined using non-compartmental approaches and considering the time-concentration profile over the complete sampling interval.
The PK analysis set contained participants who had received at least one dose of AMG 701 and had at least one PK sample collected. These participants were evaluated for PK analysis unless the number of data points required for analysis was not enough, or significant protocol deviations had affected the data, or if key dosing or sampling information was missing. Data is presented for free serum AMG 701. 99999 indicates the value was not reported due to N = 0, or N = 1 and standard deviation was not available.

End point type	Secondary

End point timeframe:

Cohorts 1 and 2: C1D1, C1D8, and C1D15;
Cohort 7: C1D1;
Cohorts 8 and 15: C1D1, C1D15, and C1D22;
All other cohorts: C1D1, C1D8, C1D15, and C1D22 (sampling pre-dose up to 120 hours post-dose; up to 144 hours post C1D8 for Cohort 16 only)

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data for all cohorts are included in the endpoint, using a combination of reporting arms and subject analysis sets.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[53]	1[54]	1[55]	3[56]
Units: hours				
median (full range (min-max))				
C1D1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 2)
C1D8	168 (168 to 168)	2 (2 to 2)	1 (1 to 1)	1 (1 to 2)
C1D15	2 (2 to 2)	2 (2 to 2)	1 (1 to 1)	1 (1 to 2)
C1D22	99999 (99999 to 99999)	99999 (99999 to 99999)	1 (1 to 1)	1 (1 to 2)

Notes:

[53] - (N=1, 1, 1, 0)

[54] - (N=1, 1, 1, 0)

[55] - (N=1, 1, 1, 1)

[56] - (N=3, 3, 3, 3)

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[57]	4[58]	1[59]	4[60]
Units: hours				
median (full range (min-max))				
C1D1	1.5 (1 to 8)	2.5 (1 to 4)	2 (2 to 2)	2 (1 to 8)
C1D8	1 (1 to 6)	2 (1 to 12)	99999 (99999 to 99999)	99999 (99999 to 99999)
C1D15	1 (1 to 24)	1 (1 to 12)	99999 (99999 to 99999)	1 (1 to 2)
C1D22	1 (1 to 4)	1 (1 to 1)	99999 (99999 to 99999)	1 (1 to 1)

Notes:

[57] - (N=4, 4, 3, 3)

[58] - (N=4, 3, 3, 3)

[59] - (N=1, 0, 0, 0)

[60] - (N=4, 0, 3, 3)

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[61]	3[62]	4[63]	8[64]
Units: hours				
median (full range (min-max))				
C1D1	1.5 (1 to 2)	120 (72 to 168)	49 (49 to 49)	49 (49 to 50)
C1D8	99999 (99999 to 99999)	2 (2 to 2)	1 (1 to 2)	1 (1 to 8)
C1D15	2 (1 to 2)	99999 (99999 to 99999)	2 (1 to 2)	2 (1 to 8)
C1D22	2 (2 to 12)	99999 (99999 to 99999)	2 (1 to 2)	2 (1 to 12)

Notes:
[61] - (N=4, 0, 3, 4)
[62] - (N=3, 1, 0, 0)
[63] - (N=4, 3, 3, 3)
[64] - (N=8, 4, 7, 7)

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 9 and Cohort 9 ext Combined
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12[65]	20[66]	9[67]	8[68]
Units: hours				
median (full range (min-max))				
C1D1	49 (2 to 60)	98 (1 to 240)	168 (49 to 240)	1 (1 to 12)
C1D8	1 (1 to 24)	2 (1 to 48)	6 (1 to 8)	1 (1 to 4)
C1D15	1.5 (1 to 48)	4 (1 to 48)	4.5 (1 to 24)	1 (1 to 2)
C1D22	3 (1 to 48)	8 (1 to 48)	5 (2 to 8)	1 (1 to 12)

Notes:
[65] - (N=12, 8, 10, 8)
[66] - (N=20, 13, 14, 14)
[67] - (N=9, 5, 4, 2)
[68] - (N=8, 8, 7, 8)

End point values	Cohort 10 and Cohort 10 ext Combined	Cohort 11 and Cohort 11 ext Combined	Cohort 12 and Cohort 12 ext Combined	Cohort 13 and Cohort 13 ext Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11[69]	7[70]	10[71]	10[72]
Units: hours				
median (full range (min-max))				
C1D1	2 (1 to 12)	1 (1 to 8)	36.5 (1 to 50)	49.5 (1 to 56)
C1D8	2 (1 to 2)	1 (1 to 2)	1.5 (1 to 4)	1 (1 to 6)
C1D15	1 (1 to 24)	1 (1 to 2)	2 (1 to 2)	1 (1 to 2)
C1D22	1 (1 to 4)	1 (1 to 2)	1 (1 to 2)	1 (1 to 2)

Notes:
[69] - (N=11, 11, 9, 8)
[70] - (N=6, 7, 5, 5)
[71] - (N=10, 8, 8, 6)
[72] - (N=10, 8, 9, 9)

End point values	Cohort 14 and Cohort 14 ext Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	14[73]			
Units: hours				
median (full range (min-max))				
C1D1	49 (1 to 56)			
C1D8	2 (1 to 8)			
C1D15	2 (1 to 8)			
C1D22	2 (1 to 4)			

Notes:

[73] - (N=14, 12, 13, 11)

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration-time Curve from Time 0 to 168 Hours (AUC168) for AMG 701

End point title	Area Under the Concentration-time Curve from Time 0 to 168 Hours (AUC168) for AMG 701[74]

End point description:

The PK parameters were determined using non-compartmental approaches and considering the time-concentration profile over the complete sampling interval.
The PK analysis set contained participants who had received at least one dose of AMG 701 and had at least one PK sample collected. These participants were evaluated for PK analysis unless the number of data points required for analysis was not enough, or significant protocol deviations had affected the data, or if key dosing or sampling information was missing. Data is presented for free serum AMG 701. 99999 indicates the value was not reported due to N = 0, or N = 1 the standard deviation was not calculated.

End point type	Secondary

End point timeframe:

Cohorts 1 and 2: C1D1, C1D8, and C1D15;
Cohort 7: C1D1;
Cohorts 8 and 15: C1D1, C1D15, and C1D22;
All other cohorts: C1D1, C1D8, C1D15, and C1D22 (sampling pre-dose up to 120 hours post-dose; up to 144 hours post C1D8 for Cohort 16 only)

Notes:

[74] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data for all cohorts are included in the endpoint, using a combination of reporting arms and subject analysis sets.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[75]	1[76]	1[77]	3[78]
Units: hr*ng/mL				
arithmetic mean (standard deviation)				
C1D1	5.99 (± 99999)	0.901 (± 99999)	59.1 (± 99999)	26.1 (± 7.15)
C1D8	3.98 (± 99999)	2.04 (± 99999)	140 (± 99999)	31.3 (± 6.5)
C1D15	25.7 (± 99999)	18.6 (± 99999)	137 (± 99999)	28.4 (± 13.1)
C1D22	99999 (± 99999)	99999 (± 99999)	132 (± 99999)	29.5 (± 13.4)

Notes:

[75] - (N=1, 1, 1, 0)

[76] - (N=1, 1, 1, 0)

[77] - (N=1, 1, 1, 1)

[78] - (N=3, 3, 3, 3)

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose

				F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[79]	4[80]	1[81]	4[82]
Units: hr*ng/mL				
arithmetic mean (standard deviation)				
C1D1	141 (± 111)	1440 (± 2060)	39.8 (± 99999)	1660 (± 1970)
C1D8	99999 (± 99999)	2670 (± 4070)	99999 (± 99999)	99999 (± 99999)
C1D15	99999 (± 99999)	4360 (± 6820)	99999 (± 99999)	4230 (± 5570)
C1D22	99999 (± 99999)	5230 (± 8180)	99999 (± 99999)	4170 (± 5490)

Notes:

[79] - (N=4, 0, 0, 0)

[80] - (N=4, 3, 3, 3)

[81] - (N=1, 0, 0, 0)

[82] - (N=3, 0, 3, 3)

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[83]	1[84]	4[85]	8[86]
Units: hr*ng/mL				
arithmetic mean (standard deviation)				
C1D1	695 (± 433)	2300 (± 99999)	27700 (± 37100)	50500 (± 74600)
C1D8	99999 (± 99999)	54900 (± 99999)	122000 (± 117000)	71700 (± 92000)
C1D15	213000 (± 179000)	99999 (± 99999)	146000 (± 131000)	177000 (± 198000)
C1D22	207000 (± 190000)	99999 (± 99999)	188000 (± 161000)	236000 (± 181000)

Notes:

[83] - (N=4, 0, 3, 4)

[84] - (N=1, 1, 0, 0)

[85] - (N=4, 3, 3, 3)

[86] - (N=8, 4, 7, 7)

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 9 and Cohort 9 ext Combined
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	12[87]	20[88]	9[89]	8[90]
Units: hr*ng/mL				
arithmetic mean (standard deviation)				
C1D1	17900 (± 32200)	31000 (± 42700)	29700 (± 63200)	437 (± 444)
C1D8	84800 (± 120000)	147000 (± 129000)	88100 (± 155000)	1570 (± 2150)
C1D15	185000 (± 189000)	212000 (± 174000)	151000 (± 238000)	2050 (± 2620)
C1D22	208000 (± 181000)	288000 (± 201000)	11900 (± 3080)	2060 (± 3470)

Notes:

[87] - (N=11, 8, 10, 8)

[88] - (N=20, 12, 14, 14)

[89] - (N=9, 4, 3, 2)

[90] - (N=7, 8, 7, 8)

End point values	Cohort 10 and Cohort 10 ext Combined	Cohort 11 and Cohort 11 ext Combined	Cohort 12 and Cohort 12 ext Combined	Cohort 13 and Cohort 13 ext Combined
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11[91]	7[92]	9[93]	10[94]
Units: hr*ng/mL				
arithmetic mean (standard deviation)				
C1D1	366 (± 353)	208 (± 254)	21600 (± 35200)	21700 (± 57800)
C1D8	4290 (± 7230)	4520 (± 6320)	54500 (± 70700)	4520 (± 5670)
C1D15	3120 (± 3770)	6240 (± 11100)	79900 (± 95400)	6930 (± 6990)
C1D22	2490 (± 3980)	9410 (± 11000)	91000 (± 114000)	30900 (± 63600)

Notes:

[91] - (N=11, 11, 9, 8)

[92] - (N=6, 7, 5, 5)

[93] - (N=9, 8, 8, 6)

[94] - (N=10, 8, 9, 9)

End point values	Cohort 14 and Cohort 14 ext Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	13[95]			
Units: hr*ng/mL				
arithmetic mean (standard deviation)				
C1D1	68400 (± 71600)			
C1D8	135000 (± 121000)			
C1D15	157000 (± 138000)			
C1D22	157000 (± 147000)			

Notes:

[95] - (N=13, 12, 13, 11)

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR) According to International Working Group Response Criteria for Multiple Myeloma (IMWG-URC)

End point title	Best Overall Response (BOR) According to International Working Group Response Criteria for Multiple Myeloma (IMWG-URC)

End point description:

BOR was the best observed disease response per IMWG-URC:

• stringent complete response (sCR): complete response (CR) criteria, normal serum free light chain ratio and no clonal cells in BM;
• CR: Negative immunofixation on serum and urine, soft tissue plasmacytomas disappearance, < 5% plasma cells in bone marrow (BM);
• very good partial response (VGPR): Serum and urine M-protein detectable by immunofixation or ≥ 90% reduction in serum M-protein (urine M-protein level < 100 mg/24-h);
• PR: ≥ 50% reduction of serum M-protein and 24-h urinary M-protein by ≥ 90% or to < 200 mg/24-h;
• minor response (MR): 25–49% reduction of serum M-protein and 50–89% in 24-h urinary M-protein;
• stable disease (SD): not meeting criteria for sCR, VGPR, PR, MR or Progressive Disease (PD);
• PD: ≥ 25% increase in serum or urine M-protein, new bone lesions, ≥ 50% increase in circulating plasma cells.
Safety analysis set included all enrolled participants who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

C1D1 to the earliest of: start of new multiple myeloma therapy, disease progression per IMWG-URC, death, or consent withdrawal; median time on study was 12.6 months.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	1	3
Units: Participants				
sCR	0	0	0	0
CR	0	0	0	0
VGPR	0	0	0	0
PR	0	0	0	0
MR	0	0	0	0
SD	0	0	1	0
PD	0	0	0	2
Not evaluable	1	1	0	1

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	1	4
Units: Participants				
sCR	0	1	0	0
CR	0	0	0	0
VGPR	0	0	0	0
PR	0	0	0	0
MR	0	0	0	0
SD	0	0	0	2
PD	3	2	0	0
Not evaluable	1	1	1	2

End point values	Cohort 9: AMG	Cohort 9	Cohort 10:	Cohort 10 ext:

	701 Dose F/Dose H	extension (ext): AMG 701 Dose F/Dose H	AMG 701 Dose F/Dose I	AMG 701 Dose F/Dose I
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	8	3
Units: Participants				
sCR	0	0	0	1
CR	0	0	0	0
VGPR	0	0	0	0
PR	0	0	2	0
MR	0	0	0	0
SD	3	2	5	1
PD	2	1	0	1
Not evaluable	0	0	1	0

End point values	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L	Cohort 12 ext: AMG 701 Dose F/Dose L
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	5
Units: Participants				
sCR	1	1	1	1
CR	0	0	1	1
VGPR	0	0	0	0
PR	0	0	0	0
MR	0	0	1	0
SD	1	0	1	2
PD	1	1	0	1
Not evaluable	1	1	1	0

End point values	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	5	9
Units: Participants				
sCR	0	1	0	1
CR	0	0	0	3
VGPR	0	0	1	0
PR	0	2	1	1
MR	0	0	0	0
SD	1	2	2	3
PD	3	1	0	1
Not evaluable	0	0	1	0

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	8
Units: Participants				
sCR	0	0	0	1
CR	1	1	2	2
VGPR	1	1	0	1
PR	0	0	0	2
MR	0	0	0	0
SD	2	0	0	2
PD	0	0	0	0
Not evaluable	0	2	2	0

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	31	10	
Units: Participants				
sCR	7	8	0	
CR	6	7	2	
VGPR	5	7	2	
PR	1	2	1	
MR	0	1	0	
SD	5	3	1	
PD	3	3	4	
Not evaluable	5	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) per IMWG-URC

End point title	Overall Response Rate (ORR) per IMWG-URC

End point description:

ORR is the percentage of analysis set participants in each treatment group with a best overall response of sCR, CR, VGPR, or PR per IMWG-UCR.
• sCR: CR and normal serum free light chain ratio and no clonal cells in BM;
• CR: Negative immunofixation on serum and urine, soft tissue plasmacytomas disappearance, < 5% plasma cells in BM;
• VGPR: Serum and urine M-protein detectable by immunofixation or ≥ 90% reduction in serum M-protein (urine M-protein level < 100 mg/24-h);
• PR: ≥ 50% reduction of serum M-protein and 24-h urinary M-protein by ≥ 90% or to < 200 mg/24-h.
Safety analysis set included all enrolled participants who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

C1D1 to the earliest of: start of new multiple myeloma therapy, disease progression per IMWG-URC, death, or consent withdrawal; median time on study was 12.6 months.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	1	3
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 97.5)	0.0 (0.0 to 97.5)	0.0 (0.0 to 97.5)	0.0 (0.0 to 70.8)

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	1	4
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 60.2)	25.0 (0.6 to 80.6)	0.0 (0.0 to 97.5)	0.0 (0.0 to 60.2)

End point values	Cohort 9: AMG 701 Dose F/Dose H	Cohort 9 extension (ext): AMG 701 Dose F/Dose H	Cohort 10: AMG 701 Dose F/Dose I	Cohort 10 ext: AMG 701 Dose F/Dose I
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	8	3
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 52.2)	0.0 (0.0 to 70.8)	25.0 (3.2 to 65.1)	33.3 (0.8 to 90.6)

End point values	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L	Cohort 12 ext: AMG 701 Dose F/Dose L
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	5
Units: percentage of participants				
number (confidence interval 95%)	25.0 (0.6 to 80.6)	33.3 (0.8 to 90.6)	40.0 (5.3 to 85.3)	40.0 (5.3 to 85.3)

End point values	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	5	9
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 60.2)	50.0 (11.8 to 88.2)	40.0 (5.3 to 85.3)	55.6 (21.2 to 86.3)

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	8
Units: percentage of participants				
number (confidence interval 95%)	50.0 (6.8 to 93.2)	50.0 (6.8 to 93.2)	50.0 (6.8 to 93.2)	75.0 (34.9 to 96.8)

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	31	10	
Units: percentage of participants				
number (confidence interval 95%)	59.4 (40.6 to 76.3)	77.4 (58.9 to 90.4)	50.0 (18.7 to 81.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) According to IMWG-URC

End point title	Duration of Response (DOR) According to IMWG-URC

End point description:

DOR was calculated as (date of first confirmed PD assessment or death or censoring - date of the first observation indicating PR [or better] + 1) / 30.4375.
PD: ≥ 25% increase in serum or urine M-protein, new bone lesions, ≥ 50% increase in circulating plasma cells.
95% confidence intervals (CIs) were estimated using the method by Klein and Moeschberger (1997) with log-log transformation. 99999 = value was not evaluable.
Safety analysis set included all enrolled participants who received at least one dose of study treatment. Data is included for participants who died or had PD.

End point type	Secondary

End point timeframe:

C1D1 to the earliest of: start of new multiple myeloma therapy, disease progression per IMWG-URC, death, or consent withdrawal; median time on study was 12.6 months.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[96]	0[97]	0[98]	0[99]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[96] - No participants died or had PD.

[97] - No participants died or had PD.

[98] - No participants died or had PD.

[99] - No participants died or had PD.

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[100]	1	0[101]	0[102]
Units: months				
median (confidence interval 95%)	(to)	99999 (99999 to 99999)	(to)	(to)

Notes:

[100] - No participants died or had PD.

[101] - No participants died or had PD.

[102] - No participants died or had PD.

End point values	Cohort 9: AMG 701 Dose F/Dose H	Cohort 9 extension (ext): AMG 701 Dose F/Dose H	Cohort 10: AMG 701 Dose F/Dose I	Cohort 10 ext: AMG 701 Dose F/Dose I
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[103]	0[104]	2	1
Units: months				
median (confidence interval 95%)	(to)	(to)	5.6 (3.7 to 99999)	99999 (99999 to 99999)

Notes:

[103] - No participants died or had PD.

[104] - No participants died or had PD.

End point values	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L	Cohort 12 ext: AMG 701 Dose F/Dose L
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	2
Units: months				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (36.6 to 99999)

End point values	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[105]	3	2	5
Units: months				
median (confidence interval 95%)	(to)	18.1 (0.99999 to 99999)	99999 (12.1 to 99999)	99999 (25.4 to 99999)

Notes:

[105] - No participants died or had PD.

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	6
Units: months				
median (confidence interval 95%)	99999 (5.6 to 99999)	99999 (3.5 to 99999)	99999 (22.3 to 99999)	8.5 (4.6 to 99999)

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	24	5	
Units: months				
median (confidence interval 95%)	99999 (15.9 to 99999)	99999 (9.8 to 99999)	10.2 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response According to IMWG-UCR

End point title	Time to Response According to IMWG-UCR

End point description:

Time to response was calculated as (date of first confirmed sCR/CR/VGPR/PR - first dose date + 1) / 30.4375.
• sCR: CR and normal serum free light chain ratio and no clonal cells in BM;
• CR: Negative immunofixation on serum and urine, soft tissue plasmacytomas disappearance, < 5% plasma cells in BM;
• VGPR: Serum and urine M-protein detectable by immunofixation or ≥ 90% reduction in serum M-protein (urine M-protein level < 100 mg/24-h);
• PR: ≥ 50% reduction of serum M-protein and 24-h urinary M-protein by ≥ 90% or to < 200 mg/24-h.
Safety analysis set included all enrolled participants who received at least one dose of study treatment. Data is presented for participants with a response of sCR, CR, VGPR or PR.

End point type	Secondary

End point timeframe:

C1D1 to the earliest of: start of new multiple myeloma therapy, disease progression per IMWG-URC, death, or consent withdrawal; median time on study was 12.6 months.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[106]	0[107]	0[108]	0[109]
Units: months				
median (inter-quartile range (Q1-Q3))	(to)	(to)	(to)	(to)

Notes:

[106] - No participants had a response of sCR, CR, VGPR or PR.

[107] - No participants had a response of sCR, CR, VGPR or PR.

[108] - No participants had a response of sCR, CR, VGPR or PR.

[109] - No participants had a response of sCR, CR, VGPR or PR.

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[110]	1	0[111]	0[112]
Units: months				
median (inter-quartile range (Q1-Q3))	(to)	1.0 (1.0 to 1.0)	(to)	(to)

Notes:

[110] - No participants had a response of sCR, CR, VGPR or PR.

[111] - No participants had a response of sCR, CR, VGPR or PR.

[112] - No participants had a response of sCR, CR, VGPR or PR.

End point values	Cohort 9: AMG 701 Dose F/Dose H	Cohort 9 extension (ext): AMG 701 Dose F/Dose H	Cohort 10: AMG 701 Dose F/Dose I	Cohort 10 ext: AMG 701 Dose F/Dose I
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[113]	0[114]	2	1
Units: months				
median (inter-quartile range (Q1-Q3))	(to)	(to)	2.3 (1.8 to 2.8)	1.0 (1.0 to 1.0)

Notes:

[113] - No participants had a response of sCR, CR, VGPR or PR.

[114] - No participants had a response of sCR, CR, VGPR or PR.

End point values	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L	Cohort 12 ext: AMG 701 Dose F/Dose L
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	2
Units: months				
median (inter-quartile range (Q1-Q3))	2.8 (2.8 to 2.8)	1.9 (1.9 to 1.9)	1.4 (1.0 to 1.9)	1.0 (1.0 to 1.0)

End point values	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[115]	3	2	5

Units: months				
median (inter-quartile range (Q1-Q3))	(to)	1.0 (1.0 to 1.9)	1.9 (1.0 to 2.8)	1.0 (1.0 to 1.1)

Notes:

[115] - No participants had a response of sCR, CR, VGPR or PR.

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	6
Units: months				
median (inter-quartile range (Q1-Q3))	1.4 (1.0 to 1.9)	1.5 (1.0 to 2.0)	1.0 (0.6 to 1.3)	1.0 (0.9 to 1.0)

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	24	5	
Units: months				
median (inter-quartile range (Q1-Q3))	1.0 (1.0 to 1.2)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS) According to IMWG-UCR

End point title	Progression Free Survival (PFS) According to IMWG-UCR

End point description:

PFS was calculated as (date of confirmed PD or death or censoring - first dose date + 1) / 30.4375.
PD: ≥ 25% increase in serum or urine M-protein, new bone lesions, ≥ 50% increase in circulating plasma cells. PFS data was censored: participants alive, no documented PD, no new anticancer therapy or procedure at time of analysis were censored at date of last study visit or the first dose date of any IP; participants alive, no documented PD, with new anticancer therapy or procedure were censored at last study visit prior to new treatment or first dose of any IP; participants with PD or death > 70 days after last study visit were censored at date of last visit prior to PD or death or first dose date of any IP.
95% CIs for medians and percentiles were estimated using the method by Klein and Moeschberger (1997) with log-log transformation. 99999=value was not evaluable.
Safety analysis set included all enrolled participants who received at least one dose of study treatment.

End point type	Secondary

End point timeframe:

C1D1 to the earliest of: start of new multiple myeloma therapy, disease progression per IMWG-URC, death, or consent withdrawal; median time on study was 12.6 months.

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	1	3
Units: months				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	3.5 (-99999 to 99999)	1.0 (1.0 to 99999)

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	1	4
Units: months				
median (confidence interval 95%)	1.0 (0.9 to 99999)	1.0 (0.9 to 99999)	0.6 (-99999 to 99999)	2.8 (1.1 to 99999)

End point values	Cohort 9: AMG 701 Dose F/Dose H	Cohort 9 extension (ext): AMG 701 Dose F/Dose H	Cohort 10: AMG 701 Dose F/Dose I	Cohort 10 ext: AMG 701 Dose F/Dose I
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	8	3
Units: months				
median (confidence interval 95%)	1.6 (1.0 to 99999)	1.9 (0.9 to 99999)	2.8 (1.3 to 5.6)	1.7 (1.1 to 99999)

End point values	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L	Cohort 12 ext: AMG 701 Dose F/Dose L
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	5	5
Units: months				
median (confidence interval 95%)	2.0 (0.3 to 99999)	1.0 (0.9 to 99999)	99999 (7.5 to 99999)	37.5 (1.0 to 99999)

End point values	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	5	9
Units: months				
median (confidence interval 95%)	1.0 (0.9 to 99999)	19.0 (0.9 to 99999)	1.9 (0.7 to 99999)	26.3 (1.1 to 99999)

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	4	8
Units: months				
median (confidence interval 95%)	4.6 (1.9 to 99999)	5.5 (1.4 to 99999)	22.9 (0.2 to 99999)	6.5 (2.3 to 10.1)

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	31	10	
Units: months				
median (confidence interval 95%)	12.0 (2.8 to 99999)	99999 (5.6 to 99999)	11.1 (0.8 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) According IMWG-UCR

End point title	Overall Survival (OS) According IMWG-UCR

End point description:

OS was calculated as (date of death or censoring - first dose date + 1) / 30.4375.
Participants without event of death were censored at their last known alive date.
95% CIs for medians and percentiles were estimated using the method by Klein and Moeschberger (1997) with log-log transformation. 99999 = value was not evaluable.
Safety analysis set included all enrolled participants who received at least one dose of study treatment.
Data is presented for participants who died.

End point type	Secondary

End point timeframe:

C1D1 to 30 days after the last dose of investigational product or end of study; median time on study was 12.6 months

End point values	Cohort 1: AMG 701 Dose A	Cohort 2: AMG 701 Dose B	Cohort 3: AMG 701 Dose C	Cohort 4: AMG 701 Dose D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[116]	1	1	3
Units: months				
median (confidence interval 95%)	(to)	6.3 (-99999 to 99999)	4.9 (-99999 to 99999)	10.6 (7.9 to 99999)

Notes:

[116] - No participants in this treatment group died.

End point values	Cohort 5: AMG 701 Dose E	Cohort 6: AMG 701 Dose F	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	1	4
Units: months				
median (confidence interval 95%)	6.1 (2.8 to 99999)	99999 (3.0 to 99999)	0.6 (-99999 to 99999)	12.4 (1.1 to 99999)

End point values	Cohort 9: AMG 701 Dose F/Dose H	Cohort 9 extension (ext): AMG 701 Dose F/Dose H	Cohort 10: AMG 701 Dose F/Dose I	Cohort 10 ext: AMG 701 Dose F/Dose I
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	7	1
Units: months				
median (confidence interval 95%)	13.9 (1.3 to 99999)	18.1 (1.9 to 99999)	14.6 (1.3 to 99999)	99999 (5.6 to 99999)

End point values	Cohort 11: AMG 701 Dose F/Dose J	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12: AMG 701 Dose F/Dose L	Cohort 12 ext: AMG 701 Dose F/Dose L
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	1	2
Units: months				
median (confidence interval 95%)	3.6 (2.2 to 99999)	6.8 (0.9 to 99999)	99999 (26.4 to 99999)	99999 (2.8 to 99999)

End point values	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	4	4
Units: months				
median (confidence interval 95%)	3.0 (1.5 to 99999)	10.7 (4.1 to 99999)	6.0 (0.7 to 99999)	26.3 (3.8 to 99999)

End point values	Cohort 15: AMG 701 Dose F/Dose O	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 14A: AMG 701 Dose F/Dose M/Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	7
Units: months				
median (confidence interval 95%)	35.3 (3.9 to 99999)	9.1 (1.4 to 99999)	99999 (0.2 to 99999)	12.9 (2.3 to 20.8)

End point values	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	8	4	
Units: months				
median (confidence interval 95%)	99999 (9.2 to 99999)	99999 (16.8 to 99999)	99999 (1.5 to 99999)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality was collected from first dose to end of study; median time on study was 12.6 months. Serious and other AEs were collected from first dose until last dose or end of study + 33 days; median duration on treatment was 4.1 months.

Adverse event reporting additional description:

The safety analysis set included all enrolled participants who received at least one dose of AMG 701.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Cohort 5: AMG 701 Dose E

Reporting group description:

AMG 701 Dose E was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Reporting group title	Cohort 4: AMG 701 Dose D

Reporting group description:

AMG 701 Dose D was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Reporting group title	Cohort 3: AMG 701 Dose C

Reporting group description:

AMG 701 Dose C was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Reporting group title	Cohort 2: AMG 701 Dose B

Reporting group description:

AMG 701 Dose B was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Reporting group title	Cohort 1: AMG 701 Dose A

Reporting group description:

AMG 701 Dose A was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Reporting group title	Cohort 6: AMG 701 Dose F

Reporting group description:

AMG 701 Dose F was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Reporting group title	Cohort 7: AMG 701 Dose H

Reporting group description:

AMG 701 Dose H was administered as a weekly IV infusion in a 4-week cycle with no step dosing.

Reporting group title	Cohort 8: AMG 701 Dose F/Dose G

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose G weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 11: AMG 701 Dose F/Dose J

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose J weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 10 ext: AMG 701 Dose F/Dose I

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose I weekly from C1D5 (4-week cycle).

Reporting group title	Cohort 10: AMG 701 Dose F/Dose I

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose I weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 9 extension (ext): AMG 701 Dose F/Dose H

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose H weekly from C1D5 (4-week cycle).

Reporting group title	Cohort 9: AMG 701 Dose F/Dose H

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose H weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 11 ext: AMG 701 Dose F/Dose J

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose J weekly from C1D5 (4-week cycle).

Reporting group title	Cohort 12 ext: AMG 701 Dose F/Dose L

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose L weekly from C1D3 (4-week cycle).

Reporting group title	Cohort 12: AMG 701 Dose F/Dose L

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose L weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 13: AMG 701 Dose F/Dose M

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose M weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 13 ext: AMG 701 Dose F/Dose M

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose M weekly from C1D3 (4-week cycle).

Reporting group title	Cohort 14: AMG 701 Dose F/Dose N

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose N weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 14 ext: AMG 701 Dose F/Dose N

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose N weekly from C1D3 (4-week cycle).

Reporting group title	Cohort 15: AMG 701 Dose F/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with one-step dosing. Participants received AMG 701 Dose F on C1D1 and AMG 701 Dose O weekly from C1D8 (4-week cycle).

Reporting group title	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N

Reporting group description:

AMG 701 Dose G/day was administered as an eIV infusion over 7 days and participants received AMG 701 Dose N weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 15A: AMG 701 Dose F/Dose M/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose M on C1D3, and AMG 701 Dose O weekly from C1D8 (4-week cycle).

Reporting group title	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose K on C1D3, and AMG 701 Dose O weekly from C1D8 (4-week cycle). Group 1 included participants who did not receive a prior BCMA targeting therapy.

Reporting group title	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with three-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose J on C1D3, AMG 701 Dose M on C1D5, and AMG 701 Dose O weekly from C1D8 (4-week cycle). Group 2 included participants who had relapsed or were intolerant to prior

BCMA targeting therapy.

Reporting group title	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O

Reporting group description:

AMG 701 was administered as an IV infusion with three-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose J on C1D3, AMG 701 Dose M on C1D5, and AMG 701 Dose O weekly from C1D8 (4-week cycle). Group 1 included participants who did not receive a prior BCMA targeting therapy.

Reporting group title	Cohort 14A: AMG 701 Dose F/Dose M/Dose N

Reporting group description:

AMG 701 was administered as an IV infusion with two-step dosing. Participants received AMG 701 Dose F on C1D1, AMG 701 Dose M on C1D3, and AMG 701 Dose N weekly from C1D8 (4-week cycle).

Serious adverse events	Cohort 5: AMG 701 Dose E	Cohort 4: AMG 701 Dose D	Cohort 3: AMG 701 Dose C
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	0 / 1 (0.00%)
number of deaths (all causes)	2	3	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma stage II			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Brain herniation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 limb fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			

Cardiac failure chronic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Hydrocephalus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Segmental diverticular colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialocele			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Back pain			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 chorioretinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 viraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated mycobacterium avium complex infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 disseminated			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 discitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
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 haemophilus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 klebsiella			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 fungal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
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			
Dehydration			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 2: AMG 701 Dose B	Cohort 1: AMG 701 Dose A	Cohort 6: AMG 701 Dose F
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	2 / 4 (50.00%)
number of deaths (all causes)	1	0	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma stage II			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
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, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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			
Confusional state			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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			
Brain herniation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 limb fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spinal cord injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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			
Cardiac failure chronic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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			
Hydrocephalus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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			
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Segmental diverticular colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialocele			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 chorioretinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 viraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated mycobacterium avium complex infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 disseminated			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 discitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 klebsiella			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 fungal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G	Cohort 11: AMG 701 Dose F/Dose J
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	2 / 4 (50.00%)	2 / 4 (50.00%)
number of deaths (all causes)	1	4	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma stage II			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (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 disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Brain herniation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 limb fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Cardiac failure chronic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			

Hydrocephalus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Colitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 acute			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Segmental diverticular colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialocele			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 chorioretinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 viraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated mycobacterium avium complex infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 disseminated			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 discitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 klebsiella			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 fungal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 10 ext: AMG	Cohort 10: AMG 701	Cohort 9 extension

	701 Dose F/Dose I	Dose F/Dose I	(ext): AMG 701 Dose F/Dose H
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	4 / 8 (50.00%)	1 / 3 (33.33%)
number of deaths (all causes)	1	7	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma stage II			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
Brain herniation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 limb fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac disorders			
Cardiac failure chronic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
Hydrocephalus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (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
Pancreatitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Segmental diverticular colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialocele			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 chorioretinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 viraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated mycobacterium avium complex infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 disseminated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 discitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (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
Pharyngotonsillitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 klebsiella			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 fungal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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 infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 9: AMG 701 Dose F/Dose H	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12 ext: AMG 701 Dose F/Dose L
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)	2 / 3 (66.67%)	3 / 5 (60.00%)
number of deaths (all causes)	4	2	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma stage II			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (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

Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Brain herniation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 limb fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			

Cardiac failure chronic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (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
Ventricular fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Hydrocephalus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 acute			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Segmental diverticular colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Back pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 chorioretinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 viraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated mycobacterium avium complex infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 disseminated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
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 discitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
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	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 klebsiella			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pseudomonal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 fungal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
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 respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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			
Dehydration			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
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 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 12: AMG 701 Dose F/Dose L	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)	3 / 4 (75.00%)	5 / 6 (83.33%)
number of deaths (all causes)	1	3	6
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma stage II			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	2 / 5 (40.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Confusional state			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Brain herniation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Cardiac failure chronic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Hydrocephalus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (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
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 acute			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Segmental diverticular colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 chorioretinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus viraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated mycobacterium avium complex infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Herpes zoster disseminated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 klebsiella			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 fungal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N	Cohort 15: AMG 701 Dose F/Dose O
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 5 (80.00%)	7 / 9 (77.78%)	1 / 4 (25.00%)
number of deaths (all causes)	4	4	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma stage II			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (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
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Brain herniation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 limb fracture			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Cardiac failure chronic			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			

Hydrocephalus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (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
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Colitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 acute			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Segmental diverticular colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (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
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 chorioretinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 viraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated mycobacterium avium complex infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 disseminated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 discitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			

subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
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 haemophilus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 klebsiella			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 fungal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
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 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	eIV Cohort: AMG	Cohort 15A: AMG	Cohort 15B Group 1:

	701 Dose G/day (7-day eIV) + Dose N	701 Dose F/Dose M/Dose O	AMG 701 Dose F/Dose K/Dose O
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	5 / 8 (62.50%)	23 / 32 (71.88%)
number of deaths (all causes)	3	7	11
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma stage II			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	5 / 32 (15.63%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 5
Squamous cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	3 / 32 (9.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 4 (25.00%)	2 / 8 (25.00%)	2 / 32 (6.25%)
occurrences causally related to treatment / all	1 / 1	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 32 (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
Investigations			
Blood bilirubin increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain herniation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 limb fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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			
Cardiac failure chronic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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			
Hydrocephalus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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			
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Segmental diverticular colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialocele			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis perforated			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	3 / 32 (9.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	3 / 32 (9.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 chorioretinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 viraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated mycobacterium avium complex infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 disseminated			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 klebsiella			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (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
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	3 / 32 (9.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 1
Septic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 fungal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
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 infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
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 bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 14A: AMG 701 Dose F/Dose M/Dose N
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 10 (70.00%)	21 / 31 (67.74%)	3 / 4 (75.00%)
number of deaths (all causes)	4	8	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma stage II			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	1 / 10 (10.00%)	4 / 31 (12.90%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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	1 / 10 (10.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	2 / 10 (20.00%)	2 / 31 (6.45%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (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
Pulmonary embolism			
subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (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
Respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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			
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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			
Brain herniation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
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 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (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
Lower limb fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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			

Cardiac failure chronic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (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
Ventricular fibrillation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Nervous system disorders			
Hydrocephalus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
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 and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (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
Febrile neutropenia			
subjects affected / exposed	4 / 10 (40.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	3 / 4	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neutropenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (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
Thrombocytopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 acute			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (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
Segmental diverticular colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialocele			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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			
Back pain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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			
Appendicitis perforated			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (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
COVID-19			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
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	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			

subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (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 chorioretinitis			
subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 viraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated mycobacterium avium complex infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster disseminated			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 discitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 10 (0.00%)	3 / 31 (9.68%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (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
Pneumonia bacterial			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (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 klebsiella			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (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 respiratory syncytial viral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (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
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (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
Sinusitis fungal			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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			
Dehydration			

subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
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	Cohort 5: AMG 701 Dose E	Cohort 4: AMG 701 Dose D	Cohort 3: AMG 701 Dose C
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	3 / 3 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma in situ			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Metastasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ocular neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Disease progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
Infusion site extravasation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pyrexia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	3 / 4 (75.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	5	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Atelectasis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Organising pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0

Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Delirium febrile			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Depression			

subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Mental status changes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood bicarbonate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bordetella test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Clostridium test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Glucose urine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Human rhinovirus test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza A virus test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lipase			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutrophil count			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Incorrect drug administration rate			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Incorrect product administration duration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary tract injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Tooth fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cardiac arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Nodal rhythm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Right ventricular dysfunction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tachyarrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Tachycardia			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Facial nerve disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Neurotoxicity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 4 (75.00%)	3 / 3 (100.00%)	0 / 1 (0.00%)
occurrences (all)	12	5	0
Coagulopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Coombs negative haemolytic anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperviscosity syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypofibrinogenaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Monocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Monocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	1 / 1 (100.00%)
occurrences (all)	3	4	2
Thrombocytopenia			
subjects affected / exposed	3 / 4 (75.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	12	7	2
Thrombocytopenic purpura			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blindness unilateral			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Epiretinal membrane			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Optic neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	3 / 4 (75.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	1	1	1

Dental caries			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Duodenitis haemorrhagic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gingival disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Ileus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Hypoaesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sialocele			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic fibrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash morbilliform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin disorder			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin sensitisation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Urine flow decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flank pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuropathic muscular atrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal instability			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Asymptomatic bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abscess jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemophilus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Polyomavirus viraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Prostatic abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Salmonellosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sepsis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Septic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinobronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection enterococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperammonaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	2	0
Hyperchloraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypervolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Iron overload			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Malnutrition			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Cohort 2: AMG 701 Dose B	Cohort 1: AMG 701 Dose A	Cohort 6: AMG 701 Dose F
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	1 / 1 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma in situ			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ocular neoplasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Plasma cell myeloma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Disease progression			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	3
Infusion site extravasation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	4 / 4 (100.00%)
occurrences (all)	0	0	6
Drug hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nasal congestion			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Organising pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Depressed mood			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium febrile			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Mental status changes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	3
Blood bicarbonate decreased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bordetella test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood uric acid increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Cytomegalovirus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucose urine			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Human rhinovirus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza A virus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Foot fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incorrect drug administration rate			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incorrect product administration duration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Infusion related reaction			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac arrest			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nodal rhythm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Right ventricular dysfunction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Sinus bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Tachyarrhythmia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Facial nerve disorder			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Coagulopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Coombs negative haemolytic anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperviscosity syndrome			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypofibrinogenaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Monocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Monocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	7
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Thrombocytopenic purpura			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hypoacusis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Epiretinal membrane			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eyelid ptosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Optic neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	5
Dental caries			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Duodenitis haemorrhagic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sialocele			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Hepatic fibrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Drug eruption			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash morbilliform			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Rash pruritic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin sensitisation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Chronic kidney disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Bone pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck mass			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathic muscular atrophy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal instability			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abscess jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Clostridium difficile infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemophilus infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pneumonia aspiration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polyomavirus viraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostatic abscess			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pyuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Salmonellosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Septic shock			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinobronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	4
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vaginal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperammonaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperchloraemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypomagnesaemia			

subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Hypophagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron overload			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 7: AMG 701 Dose H	Cohort 8: AMG 701 Dose F/Dose G	Cohort 11: AMG 701 Dose F/Dose J
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	4 / 4 (100.00%)	4 / 4 (100.00%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma in situ			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastasis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ocular neoplasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Catheter site pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Chest pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Disease progression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	3 / 4 (75.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Infusion site extravasation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	3 / 4 (75.00%)
occurrences (all)	1	1	12
Drug hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Organising pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nasal dryness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium febrile			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Mental status changes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			

subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bicarbonate decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Bordetella test positive			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Glucose urine			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Human rhinovirus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza A virus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Platelet count decreased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0

SARS-CoV-2 test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hand fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incorrect drug administration rate			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incorrect product administration duration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Subdural haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Spinal compression fracture			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sunburn			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract injury			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Transfusion reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac arrest			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nodal rhythm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Right ventricular dysfunction			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachyarrhythmia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Facial nerve disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	3 / 4 (75.00%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Memory impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1 (100.00%)	2 / 4 (50.00%)	2 / 4 (50.00%)
occurrences (all)	5	5	5
Coagulopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Coombs negative haemolytic anaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperviscosity syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypofibrinogenaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	5
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	6
Iron deficiency anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Monocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Monocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	3 / 4 (75.00%)
occurrences (all)	0	0	7
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Thrombocytopenic purpura			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cataract			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epiretinal membrane			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Episcleritis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Optic neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	3 / 4 (75.00%)	1 / 4 (25.00%)
occurrences (all)	0	4	1
Dental caries			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Duodenitis haemorrhagic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ileus			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sialocele			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic fibrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eczema			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Neurodermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash morbilliform			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin sensitisation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			

subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urine flow decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathic muscular atrophy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal instability			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sacral pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abscess jaw			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Haemophilus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polyomavirus viraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostatic abscess			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pseudomonas infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Salmonellosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Septic shock			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinobronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	3 / 4 (75.00%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dehydration			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperammonaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperchloraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	6	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	3
Hyperphosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypervolaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 4 (75.00%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Hypomagnesaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypophagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Iron deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron overload			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 10 ext: AMG 701 Dose F/Dose I	Cohort 10: AMG 701 Dose F/Dose I	Cohort 9 extension (ext): AMG 701 Dose F/Dose H
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	8 / 8 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma in situ			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metastasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	3 / 8 (37.50%)	1 / 3 (33.33%)
occurrences (all)	0	3	2
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			

subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	0	2	3
Disease progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	2 / 8 (25.00%)	1 / 3 (33.33%)
occurrences (all)	1	2	2
Infusion site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			

subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 3 (66.67%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Pyrexia			
subjects affected / exposed	2 / 3 (66.67%)	3 / 8 (37.50%)	0 / 3 (0.00%)
occurrences (all)	3	4	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 3 (33.33%)	3 / 8 (37.50%)	1 / 3 (33.33%)
occurrences (all)	2	6	1
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	4 / 8 (50.00%)	1 / 3 (33.33%)
occurrences (all)	0	5	2
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Laryngeal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Organising pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Sinus pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Stridor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Delirium febrile			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			

Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	1	3	1
Blood bicarbonate decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Bordetella test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cytomegalovirus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Glucose urine			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Heart rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Human rhinovirus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza A virus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	6	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	0	1	1

Neutrophil count			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	1	3	1
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Urine output decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Fall			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Humerus fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Incorrect drug administration rate			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Incorrect product administration duration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	3
Sunburn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac arrest			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nodal rhythm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Right ventricular dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachyarrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Facial nerve disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	9	0
Hypoaesthesia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Muscle spasticity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nervous system disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Neurotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	6 / 8 (75.00%)	2 / 3 (66.67%)
occurrences (all)	2	17	18
Coagulopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Coombs negative haemolytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperviscosity syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypofibrinogenaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Monocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Monocytosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	0	3	8
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	0	1	11
Thrombocytopenic purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epiretinal membrane			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Optic neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	3 / 3 (100.00%)
occurrences (all)	0	1	3
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	3 / 8 (37.50%)	3 / 3 (100.00%)
occurrences (all)	1	5	4
Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Duodenitis haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gingival disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Ileus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sialocele			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Hepatobiliary disorders			
Hepatic fibrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Alopecia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash morbilliform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin sensitisation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	2 / 3 (66.67%)
occurrences (all)	3	0	2
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Neuropathic muscular atrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Pain in jaw			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal instability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Synovitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abscess jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Erysipelas			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemophilus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polyomavirus viraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prostatic abscess			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Salmonellosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			

subjects affected / exposed	1 / 3 (33.33%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Sinobronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperammonaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	1 / 3 (33.33%)
occurrences (all)	0	4	3
Hyperchloraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	8	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 8 (25.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypervolaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	2 / 3 (66.67%)
occurrences (all)	0	1	11
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	3 / 8 (37.50%)	2 / 3 (66.67%)
occurrences (all)	2	3	14
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron overload			

subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	1 / 3 (33.33%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lactic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 8 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 8 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Cohort 9: AMG 701 Dose F/Dose H	Cohort 11 ext: AMG 701 Dose F/Dose J	Cohort 12 ext: AMG 701 Dose F/Dose L
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	3 / 3 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	3
Bowen's disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Malignant melanoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Malignant melanoma in situ			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metastasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metastatic squamous cell carcinoma			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Ocular neoplasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	4
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Hypotension			
subjects affected / exposed	2 / 5 (40.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	5	1	0

Orthostatic hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Disease progression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Generalised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	4 / 5 (80.00%)
occurrences (all)	0	0	4
Infusion site extravasation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hernia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypothermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	3 / 5 (60.00%)
occurrences (all)	0	1	4
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 5 (20.00%)	2 / 3 (66.67%)	4 / 5 (80.00%)
occurrences (all)	2	7	6

Drug hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Organising pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Paranasal sinus discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pulmonary oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Upper-airway cough syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Delirium			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Delirium febrile			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	2 / 5 (40.00%)
occurrences (all)	1	1	3
Mental status changes			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 5 (40.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	4	0	1
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 5 (40.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Blood bicarbonate decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood creatine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Bordetella test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram ST segment elevation			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	4	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Glucose urine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Human rhinovirus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza A virus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigation			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophil count			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	5	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Serum ferritin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Incorrect drug administration rate			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Incorrect product administration duration			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	9	0	7
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Ligament sprain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle strain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Sunburn			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Atrial flutter			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nodal rhythm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Right ventricular dysfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachyarrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0

Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Cauda equina syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Facial nerve disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	2 / 5 (40.00%)	1 / 3 (33.33%)	3 / 5 (60.00%)
occurrences (all)	2	1	9
Hypoaesthesia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Memory impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Muscle spasticity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Neurotoxicity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	3
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Syncope			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 5 (80.00%)	1 / 3 (33.33%)	3 / 5 (60.00%)
occurrences (all)	25	3	6
Coagulopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Coombs negative haemolytic anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Febrile neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Hyperviscosity syndrome			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypofibrinogenaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukopenia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Monocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Monocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	4	4	2
Thrombocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	8	1	0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cataract			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Epiretinal membrane			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Eyelid ptosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Optic neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retinopathy			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	2
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 5 (40.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	1 / 5 (20.00%)	2 / 3 (66.67%)	1 / 5 (20.00%)
occurrences (all)	1	2	1
Dental caries			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Duodenitis haemorrhagic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gingival disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 5 (40.00%)	1 / 3 (33.33%)	3 / 5 (60.00%)
occurrences (all)	2	2	3
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Paraesthesia oral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Proctalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sialocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic fibrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0

Pain of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash morbilliform			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin lesion			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Skin sensitisation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Renal cyst			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	2
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Bone pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Bursitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Greater trochanteric pain syndrome			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Joint effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Neck mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuropathic muscular atrophy			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Osteonecrosis of jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rheumatoid arthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal instability			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sacral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Abscess jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Eye infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Haemophilus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Labyrinthitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Oesophageal candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Onychomycosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			

subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Polyomavirus viraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Prostatic abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	2 / 5 (40.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Pyuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Salmonellosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Septic shock			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sinobronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	2 / 5 (40.00%)
occurrences (all)	0	1	2
Urinary tract infection bacterial			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Vaginal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperammonaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperchloraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Hypervolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	2 / 5 (40.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 5 (20.00%)	2 / 3 (66.67%)	1 / 5 (20.00%)
occurrences (all)	8	5	2
Hypomagnesaemia			
subjects affected / exposed	2 / 5 (40.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Hypophagia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	4	1	0
Hypophosphataemia			

subjects affected / exposed	3 / 5 (60.00%)	1 / 3 (33.33%)	2 / 5 (40.00%)
occurrences (all)	7	1	4
Iron deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypovolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron overload			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 12: AMG 701 Dose F/Dose L	Cohort 13: AMG 701 Dose F/Dose M	Cohort 13 ext: AMG 701 Dose F/Dose M
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	4 / 4 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma in situ			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Metastasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ocular neoplasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Hot flush			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	0	2	4
Hypotension			
subjects affected / exposed	1 / 5 (20.00%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	2	3	2
Orthostatic hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Catheter site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 5 (40.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	4	1	0
Disease progression			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Generalised oedema			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Infusion site extravasation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Pyrexia			
subjects affected / exposed	2 / 5 (40.00%)	1 / 4 (25.00%)	3 / 6 (50.00%)
occurrences (all)	3	1	15
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	4 / 5 (80.00%)	4 / 4 (100.00%)	6 / 6 (100.00%)
occurrences (all)	10	8	16
Drug hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vaginal discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Acute respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	8	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Laryngeal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Organising pneumonia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Sinus congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Depressed mood			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Delirium febrile			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Mental status changes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	2 / 4 (50.00%)	2 / 6 (33.33%)
occurrences (all)	10	4	3
Amylase increased			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	20	0	2
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	12	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	2 / 4 (50.00%)	2 / 6 (33.33%)
occurrences (all)	12	5	6
Blood bicarbonate decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	4
Blood phosphorus decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bordetella test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3

Cytomegalovirus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	9	0	0
Glucose urine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hepatic enzyme increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Human rhinovirus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza A virus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lipase			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	3 / 5 (60.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	50	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Liver function test abnormal			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	5
Neutrophil count			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	2

Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Fall			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Incorrect drug administration rate			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Incorrect product administration duration			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	28	0	0
Infusion related reaction			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Ligament sprain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Subdural haematoma			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Stress fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urinary tract injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			

subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Atrial flutter			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nodal rhythm			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Right ventricular dysfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Tachyarrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	3
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Facial nerve disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Facial paresis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Neurotoxicity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	1 / 5 (20.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			

subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 5 (100.00%)	2 / 4 (50.00%)	4 / 6 (66.67%)
occurrences (all)	9	5	4
Coagulopathy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Coombs negative haemolytic anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hyperviscosity syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypofibrinogenaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Leukopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	4
Iron deficiency anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Monocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Monocytosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	3 / 5 (60.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	16	0	3
Thrombocytopenia			
subjects affected / exposed	3 / 5 (60.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	16	1	0
Thrombocytopenic purpura			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Ear pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Epiretinal membrane			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Episcleritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Optic neuropathy			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	2
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Diarrhoea			
subjects affected / exposed	2 / 5 (40.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	6	2	4
Dental caries			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Duodenitis haemorrhagic			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival disorder			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 5 (60.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	7	1	2

Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oral dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sialocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Hepatobiliary disorders			
Hepatic fibrosis			

subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperbilirubinaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Neurodermatitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rash morbilliform			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Skin lesion			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skin exfoliation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin sensitisation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	0	2	3
Chronic kidney disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Micturition disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Urine flow decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bursitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathic muscular atrophy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	4	0	1
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Spinal instability			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abscess jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Candida infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection reactivation			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Diarrhoea infectious			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemophilus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	2
Otitis externa			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Parvovirus B19 infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Polyomavirus viraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Prostatic abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pulpitis dental			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Salmonellosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rhinovirus infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Sputum purulent			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Sinobronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1

Urinary tract infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperammonaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Hyperchloraemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	3 / 6 (50.00%)
occurrences (all)	0	0	7
Hyperkalaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypernatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypermagnesaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	2
Hypervolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Hypocalcaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 5 (40.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	2	3	5
Hypomagnesaemia			
subjects affected / exposed	3 / 5 (60.00%)	2 / 4 (50.00%)	4 / 6 (66.67%)
occurrences (all)	5	5	8
Hypophagia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	3 / 5 (60.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	9	2	3
Iron deficiency			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypovolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Iron overload			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lactic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 14: AMG 701 Dose F/Dose N	Cohort 14 ext: AMG 701 Dose F/Dose N	Cohort 15: AMG 701 Dose F/Dose O
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	9 / 9 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Basal cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma in situ			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ocular neoplasm			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	1 / 5 (20.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Orthostatic hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Phlebitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	0	3	1
Disease progression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	3 / 5 (60.00%)	3 / 9 (33.33%)	1 / 4 (25.00%)
occurrences (all)	3	4	1
Infusion site extravasation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Oedema			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	2 / 5 (40.00%)	3 / 9 (33.33%)	2 / 4 (50.00%)
occurrences (all)	6	8	2
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	5 / 5 (100.00%)	8 / 9 (88.89%)	4 / 4 (100.00%)
occurrences (all)	15	21	13
Drug hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Prostatomegaly			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	2 / 5 (40.00%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	2	4	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	2 / 5 (40.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Organising pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	2 / 5 (40.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Sinus congestion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sinus pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	1	0

Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Delirium			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium febrile			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Blood bicarbonate decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bordetella test positive			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cytomegalovirus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Clostridium test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glucose urine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Human rhinovirus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza A virus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	16	0
Neutrophil count			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

SARS-CoV-2 test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Urine output decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Fall			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Foot fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incorrect drug administration rate			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incorrect product administration duration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	0	2	2
Ligament sprain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Joint dislocation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rib fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Subdural haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Spinal compression fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Atrial flutter			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac arrest			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cardiac failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Nodal rhythm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Right ventricular dysfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachyarrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cognitive disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Facial nerve disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 5 (60.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	5	6	0
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 5 (40.00%)	6 / 9 (66.67%)	3 / 4 (75.00%)
occurrences (all)	6	31	4
Coagulopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Coombs negative haemolytic anaemia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hyperviscosity syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypofibrinogenaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Lymphopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Monocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Monocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	3 / 5 (60.00%)	6 / 9 (66.67%)	2 / 4 (50.00%)
occurrences (all)	17	31	7
Thrombocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	3 / 9 (33.33%)	1 / 4 (25.00%)
occurrences (all)	2	9	1

Thrombocytopenic purpura			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epiretinal membrane			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Episcleritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Optic neuropathy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Retinopathy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Visual impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Colitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 5 (20.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 5 (40.00%)	2 / 9 (22.22%)	2 / 4 (50.00%)
occurrences (all)	3	6	4
Dental caries			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Duodenitis haemorrhagic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 5 (60.00%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	4	3	1
Ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Paraesthesia oral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sialocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Hepatobiliary disorders			
Hepatic fibrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Drug eruption			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			

subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Erythema multiforme			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	2 / 5 (40.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Pain of skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Rash			
subjects affected / exposed	2 / 5 (40.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0

Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Rash erythematous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash morbilliform			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Skin disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin sensitisation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			

subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Chronic kidney disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Micturition disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Renal cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urine flow decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 5 (60.00%)	2 / 9 (22.22%)	1 / 4 (25.00%)
occurrences (all)	7	2	2
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	2	3	0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bursitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Joint stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Muscular weakness			

subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathic muscular atrophy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal instability			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sacral pain			

subjects affected / exposed	2 / 5 (40.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Spinal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Tenosynovitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Abscess jaw			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Candida infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eye infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Escherichia sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemophilus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Otitis externa			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Polyomavirus viraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostatic abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Salmonellosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sputum purulent			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sinobronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Staphylococcal infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	2 / 4 (50.00%)
occurrences (all)	0	1	2
Urinary tract infection bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Dehydration			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperammonaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperchloraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 9 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 5 (0.00%)	3 / 9 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Hypervolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hypocalcaemia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	1 / 5 (20.00%)	5 / 9 (55.56%)	2 / 4 (50.00%)
occurrences (all)	1	11	3
Hypomagnesaemia			
subjects affected / exposed	1 / 5 (20.00%)	4 / 9 (44.44%)	2 / 4 (50.00%)
occurrences (all)	1	9	5
Hypophagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Hypophosphataemia			
subjects affected / exposed	3 / 5 (60.00%)	5 / 9 (55.56%)	4 / 4 (100.00%)
occurrences (all)	8	18	8
Iron deficiency			
subjects affected / exposed	1 / 5 (20.00%)	0 / 9 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Hypovolaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 9 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Iron overload			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 9 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	eIV Cohort: AMG 701 Dose G/day (7-day eIV) + Dose N	Cohort 15A: AMG 701 Dose F/Dose M/Dose O	Cohort 15B Group 1: AMG 701 Dose F/Dose K/Dose O
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	8 / 8 (100.00%)	32 / 32 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Bowen's disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma in situ			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Metastasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Ocular neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Squamous cell carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	1 / 4 (25.00%)	4 / 8 (50.00%)	5 / 32 (15.63%)
occurrences (all)	1	4	11
Orthostatic hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	4 / 32 (12.50%)
occurrences (all)	0	0	5
Disease progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	8 / 32 (25.00%)
occurrences (all)	1	3	15
Infusion site extravasation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Localised oedema			

subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 32 (3.13%)
occurrences (all)	0	3	1
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	5
Oedema peripheral			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	3 / 32 (9.38%)
occurrences (all)	1	1	3
Pyrexia			
subjects affected / exposed	3 / 4 (75.00%)	3 / 8 (37.50%)	8 / 32 (25.00%)
occurrences (all)	3	4	16
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	4 / 4 (100.00%)	7 / 8 (87.50%)	25 / 32 (78.13%)
occurrences (all)	12	15	45
Drug hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1

Hypogammaglobulinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 4 (25.00%)	2 / 8 (25.00%)	9 / 32 (28.13%)
occurrences (all)	1	2	16
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	5
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 32 (6.25%)
occurrences (all)	0	1	2
Organising pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Paranasal sinus discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 32 (6.25%)
occurrences (all)	0	1	2
Pulmonary oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	3
Sinus pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	3
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 32 (3.13%)
occurrences (all)	0	1	1
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Delirium febrile			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	4 / 32 (12.50%)
occurrences (all)	1	0	4
Mental status changes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Investigations			

Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	6 / 32 (18.75%)
occurrences (all)	4	0	12
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	3 / 32 (9.38%)
occurrences (all)	0	1	5
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 4 (25.00%)	2 / 8 (25.00%)	2 / 32 (6.25%)
occurrences (all)	1	2	3
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	6 / 32 (18.75%)
occurrences (all)	3	0	13
Blood bicarbonate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	2	0
Blood bilirubin increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	2
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 32 (6.25%)
occurrences (all)	0	3	4
Blood phosphorus decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	11
Blood fibrinogen decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Blood potassium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	4 / 32 (12.50%)
occurrences (all)	0	0	7
Bordetella test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	5
Glucose urine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Human rhinovirus test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Influenza A virus test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lipase			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
International normalised ratio increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Investigation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	8 / 32 (25.00%)
occurrences (all)	0	11	44

Neutrophil count			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 4 (25.00%)	3 / 8 (37.50%)	9 / 32 (28.13%)
occurrences (all)	1	13	20
Platelet count decreased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	10 / 32 (31.25%)
occurrences (all)	1	1	20
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Serum ferritin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	4
Urinary occult blood positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	5 / 32 (15.63%)
occurrences (all)	0	5	25
Urine output decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Fall			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Incorrect drug administration rate			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Incorrect product administration duration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 32 (6.25%)
occurrences (all)	0	2	4
Ligament sprain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Skin laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Subdural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Urinary tract injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 32 (3.13%)
occurrences (all)	0	2	1
Atrial flutter			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Cardiac arrest			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nodal rhythm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Right ventricular dysfunction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	3 / 32 (9.38%)
occurrences (all)	0	2	4
Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Tachyarrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	5
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	4 / 32 (12.50%)
occurrences (all)	0	0	5
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Facial nerve disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	13 / 32 (40.63%)
occurrences (all)	0	3	20
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1

Muscle spasticity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 32 (6.25%)
occurrences (all)	0	1	2
Neurotoxicity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	1
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	3 / 8 (37.50%)	1 / 32 (3.13%)
occurrences (all)	0	4	2
Restless legs syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 4 (50.00%)	4 / 8 (50.00%)	19 / 32 (59.38%)
occurrences (all)	4	5	44
Coagulopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Coombs negative haemolytic anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	3	0	1
Hyperviscosity syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypofibrinogenaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	14
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	16
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Monocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Monocytosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	10 / 32 (31.25%)
occurrences (all)	0	4	63
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	6 / 32 (18.75%)
occurrences (all)	0	1	25
Thrombocytopenic purpura			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	3
Hypoacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Conjunctival haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Epiretinal membrane			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Episcleritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Optic neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Retinopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	1	0	2
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	4
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	3
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	5 / 32 (15.63%)
occurrences (all)	0	0	7
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	4 / 8 (50.00%)	12 / 32 (37.50%)
occurrences (all)	4	7	32
Dental caries			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Duodenitis haemorrhagic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 32 (3.13%)
occurrences (all)	0	1	4
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	1	1	0
Gingival disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	3 / 4 (75.00%)	2 / 8 (25.00%)	11 / 32 (34.38%)
occurrences (all)	4	3	21
Ileus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Oral disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Sialocele			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	3
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	7 / 32 (21.88%)
occurrences (all)	1	2	10
Hepatobiliary disorders			
Hepatic fibrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Alopecia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Drug eruption			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Erythema multiforme			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Petechiae			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Purpura			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	3 / 32 (9.38%)
occurrences (all)	1	2	21
Rash			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	3 / 32 (9.38%)
occurrences (all)	0	1	4
Rash maculo-papular			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	5 / 32 (15.63%)
occurrences (all)	3	0	8
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Rash morbilliform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	2
Skin exfoliation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Skin sensitisation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Micturition disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Urinary retention			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	8 / 32 (25.00%)
occurrences (all)	1	0	9
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	4 / 32 (12.50%)
occurrences (all)	0	1	4
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	8
Bursitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	3
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Joint stiffness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Musculoskeletal stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	2
Neck mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Neuropathic muscular atrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	1	0	1
Pain in jaw			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Spinal instability			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Synovitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Tenosynovitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Abscess jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0

Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	5 / 32 (15.63%)
occurrences (all)	0	3	5
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	3
Clostridium difficile colitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	2
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Cytomegalovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Eye infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Haemophilus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Labyrinthitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	3
Onychomycosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Pneumonia aspiration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Polyomavirus viraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Prostatic abscess			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Salmonellosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Septic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	1 / 32 (3.13%)
occurrences (all)	1	1	1
Sputum purulent			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Sinusitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	4 / 32 (12.50%)
occurrences (all)	0	0	5
Sinobronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	2 / 4 (50.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	2	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	6 / 32 (18.75%)
occurrences (all)	1	1	8
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	3 / 32 (9.38%)
occurrences (all)	0	1	8
Urinary tract infection bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1

Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	4 / 32 (12.50%)
occurrences (all)	0	0	5
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Hyperammonaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Hyperchloraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	4 / 32 (12.50%)
occurrences (all)	0	1	8
Hyperkalaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	0 / 32 (0.00%)
occurrences (all)	2	3	0
Hyperphosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	4 / 32 (12.50%)
occurrences (all)	0	1	5
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 32 (6.25%)
occurrences (all)	0	1	3
Hyperuricaemia			

subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	1	0	2
Hypervolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	6 / 32 (18.75%)
occurrences (all)	0	3	10
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	10 / 32 (31.25%)
occurrences (all)	0	3	18
Hypomagnesaemia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 8 (25.00%)	7 / 32 (21.88%)
occurrences (all)	1	2	10
Hypophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	3 / 32 (9.38%)
occurrences (all)	0	1	3
Hypophosphataemia			
subjects affected / exposed	1 / 4 (25.00%)	4 / 8 (50.00%)	13 / 32 (40.63%)
occurrences (all)	1	5	31
Iron deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Hypovolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Iron overload			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 15C Group 2: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 15C Group 1: AMG 701 Dose F/Dose J/Dose M/Dose O	Cohort 14A: AMG 701 Dose F/Dose M/Dose N
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	31 / 31 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Malignant melanoma in situ			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastatic squamous cell carcinoma			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ocular neoplasm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Hypotension			
subjects affected / exposed	4 / 10 (40.00%)	5 / 31 (16.13%)	1 / 4 (25.00%)
occurrences (all)	11	8	1

Orthostatic hypotension			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Phlebitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	3 / 10 (30.00%)	8 / 31 (25.81%)	0 / 4 (0.00%)
occurrences (all)	3	21	0
Disease progression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	6 / 10 (60.00%)	12 / 31 (38.71%)	1 / 4 (25.00%)
occurrences (all)	11	17	3
Infusion site extravasation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hernia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	3 / 10 (30.00%)	4 / 31 (12.90%)	0 / 4 (0.00%)
occurrences (all)	4	5	0
Peripheral swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Oedema peripheral			
subjects affected / exposed	2 / 10 (20.00%)	3 / 31 (9.68%)	0 / 4 (0.00%)
occurrences (all)	2	4	0
Pyrexia			
subjects affected / exposed	7 / 10 (70.00%)	11 / 31 (35.48%)	1 / 4 (25.00%)
occurrences (all)	17	25	4
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	8 / 10 (80.00%)	23 / 31 (74.19%)	4 / 4 (100.00%)
occurrences (all)	11	43	16

Drug hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 10 (0.00%)	4 / 31 (12.90%)	0 / 4 (0.00%)
occurrences (all)	0	8	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Prostatomegaly			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vaginal haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	5 / 10 (50.00%)	11 / 31 (35.48%)	2 / 4 (50.00%)
occurrences (all)	6	27	5
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 10 (10.00%)	4 / 31 (12.90%)	0 / 4 (0.00%)
occurrences (all)	2	5	0
Dyspnoea exertional			
subjects affected / exposed	2 / 10 (20.00%)	6 / 31 (19.35%)	0 / 4 (0.00%)
occurrences (all)	2	8	0
Epistaxis			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Hypoxia			
subjects affected / exposed	1 / 10 (10.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	1	5	0
Laryngeal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	6 / 31 (19.35%)	0 / 4 (0.00%)
occurrences (all)	0	7	0
Organising pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 10 (10.00%)	4 / 31 (12.90%)	0 / 4 (0.00%)
occurrences (all)	1	6	0
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Paranasal sinus discomfort			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Pulmonary oedema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pulmonary hypertension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Reflux laryngitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Sinus congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Upper-airway cough syndrome			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Stridor			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	2 / 10 (20.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	2	3	0
Delirium			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium febrile			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 10 (20.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	4	2	0
Mental status changes			

subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	3 / 10 (30.00%)	5 / 31 (16.13%)	0 / 4 (0.00%)
occurrences (all)	7	7	0
Amylase increased			
subjects affected / exposed	0 / 10 (0.00%)	5 / 31 (16.13%)	0 / 4 (0.00%)
occurrences (all)	0	50	0
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 10 (30.00%)	6 / 31 (19.35%)	0 / 4 (0.00%)
occurrences (all)	7	9	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 10 (20.00%)	6 / 31 (19.35%)	0 / 4 (0.00%)
occurrences (all)	8	7	0
Blood bicarbonate decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood phosphorus decreased			

subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 10 (0.00%)	5 / 31 (16.13%)	0 / 4 (0.00%)
occurrences (all)	0	6	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
C-reactive protein increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bordetella test positive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Chest X-ray abnormal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus test positive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Glucose urine			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Human rhinovirus test positive			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Influenza A virus test positive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Lipase increased			
subjects affected / exposed	1 / 10 (10.00%)	7 / 31 (22.58%)	0 / 4 (0.00%)
occurrences (all)	9	23	0
International normalised ratio increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigation			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	6 / 10 (60.00%)	12 / 31 (38.71%)	2 / 4 (50.00%)
occurrences (all)	48	53	10
Neutrophil count			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	2 / 10 (20.00%)	6 / 31 (19.35%)	1 / 4 (25.00%)
occurrences (all)	8	12	4
Platelet count decreased			
subjects affected / exposed	2 / 10 (20.00%)	5 / 31 (16.13%)	1 / 4 (25.00%)
occurrences (all)	13	9	8
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Serum ferritin increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood positive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Weight increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	6 / 10 (60.00%)	8 / 31 (25.81%)	1 / 4 (25.00%)
occurrences (all)	20	22	6
Urine output decreased			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incorrect drug administration rate			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incorrect product administration duration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 10 (0.00%)	4 / 31 (12.90%)	0 / 4 (0.00%)
occurrences (all)	0	6	0
Ligament sprain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle strain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Atrial flutter			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Cardiac arrest			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Nodal rhythm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Right ventricular dysfunction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachyarrhythmia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	2 / 10 (20.00%)	4 / 31 (12.90%)	0 / 4 (0.00%)
occurrences (all)	6	5	0

Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cauda equina syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 10 (20.00%)	3 / 31 (9.68%)	0 / 4 (0.00%)
occurrences (all)	2	3	0
Dysgeusia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Facial nerve disorder			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Facial paresis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	6 / 10 (60.00%)	12 / 31 (38.71%)	0 / 4 (0.00%)
occurrences (all)	13	24	0
Hypoaesthesia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Neurotoxicity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 10 (10.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Restless legs syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 10 (70.00%)	20 / 31 (64.52%)	1 / 4 (25.00%)
occurrences (all)	34	56	11
Coagulopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Coombs negative haemolytic anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	2 / 10 (20.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Hyperviscosity syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypofibrinogenaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	14	0
Leukopenia			

subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Monocytopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Monocytosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	4 / 10 (40.00%)	11 / 31 (35.48%)	3 / 4 (75.00%)
occurrences (all)	27	20	7
Thrombocytopenia			
subjects affected / exposed	4 / 10 (40.00%)	11 / 31 (35.48%)	0 / 4 (0.00%)
occurrences (all)	11	29	0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blindness unilateral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract			

subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Epiretinal membrane			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Episcleritis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eye pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Optic neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinopathy			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	2 / 10 (20.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Visual impairment			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	2 / 31 (6.45%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Abdominal distension			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Colitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	4 / 10 (40.00%)	4 / 31 (12.90%)	0 / 4 (0.00%)
occurrences (all)	5	6	0
Dry mouth			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	6 / 10 (60.00%)	7 / 31 (22.58%)	2 / 4 (50.00%)
occurrences (all)	12	12	4
Dental caries			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Duodenitis haemorrhagic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	2 / 10 (20.00%)	1 / 31 (3.23%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Dysphagia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Flatulence			
subjects affected / exposed	2 / 10 (20.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Gingival disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	7 / 10 (70.00%)	10 / 31 (32.26%)	2 / 4 (50.00%)
occurrences (all)	10	20	2
Ileus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Paraesthesia oral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sialocele			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	2 / 10 (20.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Small intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 10 (40.00%)	4 / 31 (12.90%)	1 / 4 (25.00%)
occurrences (all)	5	4	1
Hepatobiliary disorders			
Hepatic fibrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic steatosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Erythema multiforme			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Pain of skin			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 10 (30.00%)	4 / 31 (12.90%)	0 / 4 (0.00%)
occurrences (all)	6	4	0
Rash			
subjects affected / exposed	1 / 10 (10.00%)	3 / 31 (9.68%)	1 / 4 (25.00%)
occurrences (all)	2	3	1
Rash maculo-papular			
subjects affected / exposed	1 / 10 (10.00%)	3 / 31 (9.68%)	1 / 4 (25.00%)
occurrences (all)	1	4	1
Rash erythematous			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash morbilliform			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin lesion			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin sensitisation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	3
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Micturition disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Renal cyst			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 10 (20.00%)	5 / 31 (16.13%)	1 / 4 (25.00%)
occurrences (all)	2	9	1
Back pain			
subjects affected / exposed	2 / 10 (20.00%)	4 / 31 (12.90%)	1 / 4 (25.00%)
occurrences (all)	4	7	1
Bone pain			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Bursitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Greater trochanteric pain syndrome			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Musculoskeletal chest pain			
subjects affected / exposed	2 / 10 (20.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	3	5	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Neck pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathic muscular atrophy			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 10 (10.00%)	4 / 31 (12.90%)	1 / 4 (25.00%)
occurrences (all)	2	11	1
Pain in jaw			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rheumatoid arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal instability			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Tenosynovitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Abscess jaw			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
COVID-19			
subjects affected / exposed	1 / 10 (10.00%)	6 / 31 (19.35%)	1 / 4 (25.00%)
occurrences (all)	1	6	1
Candida infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Cytomegalovirus infection			

subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cytomegalovirus oesophagitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Gingivitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemophilus infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Onychomycosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Otitis externa			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumonia			

subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Pneumonia aspiration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polyomavirus viraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostatic abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pseudomonas infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Salmonellosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Septic shock			

subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 10 (0.00%)	6 / 31 (19.35%)	1 / 4 (25.00%)
occurrences (all)	0	8	1
Sputum purulent			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	3 / 10 (30.00%)	4 / 31 (12.90%)	1 / 4 (25.00%)
occurrences (all)	4	6	1
Sinobronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	8 / 31 (25.81%)	1 / 4 (25.00%)
occurrences (all)	0	8	1
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	1 / 10 (10.00%)	3 / 31 (9.68%)	1 / 4 (25.00%)
occurrences (all)	1	4	1
Urinary tract infection bacterial			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Vaginal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	6 / 10 (60.00%)	5 / 31 (16.13%)	0 / 4 (0.00%)
occurrences (all)	10	7	0
Dehydration			
subjects affected / exposed	2 / 10 (20.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Hyperammonaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperchloraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	3 / 10 (30.00%)	7 / 31 (22.58%)	1 / 4 (25.00%)
occurrences (all)	3	10	2
Hyperkalaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			

subjects affected / exposed	0 / 10 (0.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Hypernatraemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypermagnesaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Hyperuricaemia			
subjects affected / exposed	2 / 10 (20.00%)	3 / 31 (9.68%)	0 / 4 (0.00%)
occurrences (all)	2	3	0
Hypervolaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 10 (20.00%)	7 / 31 (22.58%)	0 / 4 (0.00%)
occurrences (all)	7	10	0
Hypocalcaemia			
subjects affected / exposed	4 / 10 (40.00%)	9 / 31 (29.03%)	0 / 4 (0.00%)
occurrences (all)	9	27	0
Hypoglycaemia			
subjects affected / exposed	1 / 10 (10.00%)	2 / 31 (6.45%)	0 / 4 (0.00%)
occurrences (all)	4	4	0
Hypokalaemia			
subjects affected / exposed	6 / 10 (60.00%)	10 / 31 (32.26%)	3 / 4 (75.00%)
occurrences (all)	9	30	6
Hypomagnesaemia			
subjects affected / exposed	5 / 10 (50.00%)	8 / 31 (25.81%)	3 / 4 (75.00%)
occurrences (all)	15	15	5
Hypophagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	2 / 10 (20.00%)	4 / 31 (12.90%)	1 / 4 (25.00%)
occurrences (all)	5	11	3
Hypophosphataemia			

subjects affected / exposed	6 / 10 (60.00%)	19 / 31 (61.29%)	4 / 4 (100.00%)
occurrences (all)	17	70	9
Iron deficiency			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypovolaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron overload			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 31 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour lysis syndrome			
subjects affected / exposed	0 / 10 (0.00%)	1 / 31 (3.23%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 August 2017	- Tapering of steroid pre-treatment between subsequent infusions in the same treatment cycle was removed; the required steroid dose for cycles 3 and 4 was increased. - Inclusion criteria revised to specify that participants must not be candidates for regimens known to provide clinical benefit (proteasome inhibitors, immunomodulatory drugs, and, where approved and available, CD38-directed cytolytic antibodies) to be eligible for the study. - The DLT definition was revised in line with Food and Drug Administration (FDA) requests. - The requirements for access to a medical intensive care unit during participant hospitalization periods and the requirement for sites to have cytokine release syndrome (CRS) rescue medications available on site (including at least two doses of tocilizumab per participant for US sites) were added. - The Schedule of Assessment footnotes were revised to include a reference to the list of analytes to clarify that hematologic assessments included a complete blood count with differential and a comprehensive metabolic panel, chemistry assessments included uric acid and phosphorus, and coagulation assessments included prothrombin time, partial thromboplastin time and fibrinogen. - The dose recommendations for cohorts in the dose escalation part of the study were revised to be guided by the escalation with overdose control (EWOC) principle, which mandates the dose for the next cohort to have less than 25% chance of excessive toxicity. - The terms prednisone and prednisolone were consistently updated to prednisone. - Eligibility criteria relating to renal function and prior plasma cell leukemia were clarified. - The schedules of assessment footnotes were clarified. - The possibility to use historical data (obtained up to 120 days prior to treatment start) for BM karyotyping and fluorescent in situ hybridization (FISH) was added. - The requirement to report pregnancies in a male participant's partner was added.

14 November 2017	- Clarified inclusion criteria for the dose expansion part of the protocol for participants who had not received a therapeutic CD38-targeting antibody. - Clarified no dose increases for the highest dose. - Restart guidance for CRS grade 3 was added and permanent discontinuation criteria were clarified. - Requested availability of 2 doses of tocilizumab per study participant in all countries where tocilizumab is available. - The list of possible dose level review team decisions was updated. - Eligibility criteria in the protocol synopsis were updated to be in line with the full list of inclusion criteria, ie, to reflect that participants must have received established and available therapies in order to be enrolled into the study. - The restriction stating that no study participant may receive AMG 701 treatment after the end of long term follow-up of the last participant in the study was deleted. - The requirement for HIV and latent tuberculosis testing at screening was added, as well as guidance on administration of tocilizumab for CRS management in case of latent tuberculosis. - Follow up with the sponsor medical monitor in case of overdose was updated to be mandatory. - Guidance for prevention and management of tumor lysis syndrome and corresponding references were added. - Clarified that storage time for laboratory samples depended on legal requirements in a country. - A description of assessments applicable in case of implementation of a treatment-free holiday for individual participants was added. - Updated schedules of assessments to clarify that in case of extended treatment-free intervals D36 assessments were to be repeated weekly, rather than D29 assessments, that screening for FISH and karyotyping data were obtained for participants enrolled into the dose exploration part of the study, and to include creatine clearance assessment at screening. - Allowed deviation windows for soluble BCMA. - Requirements for re-consenting were clarified.
17 January 2018	- The allowed window for on-site long term follow-up visits was increased from + 3 to + 7 days. - Inclusion criteria updated to state that participants must have received at least 2 prior lines of therapy in order to clarify that 1 line of prior therapy was not sufficient for inclusion, even if it included a proteasome inhibitor, an immunomodulatory drug and a CD38-directed cytolytic antibody. - Exclusion criteria updated for the washout time for prior therapeutic antibody treatment. This was reduced from 6 to 4 weeks as 6 weeks was considered excessive for patients who received this as their last line of treatment, particularly as no impact on participant safety was expected by this shorter washout time, given the described safety profile for the currently available anti-CD38 monoclonal antibody (daratumumab). - Japan and Canada were added to the study countries and number of sites updated to approximately 30. - The equivalent dose for methylprednisone was added to the premedication guidance. - Reference to administration of investigational product via syringe pumps was removed throughout the protocol as it does not apply in this study.
19 March 2018	- Hematologic DLT criteria were modified, and febrile neutropenia grade 4 was considered a DLT, regardless of duration.

03 December 2018	- Risk assessment of AMG 701 was updated to notate CRS as an identified risk and no longer a potential risk. - Specific CRS guidance was updated. - Permanent discontinuation of AMG 701 language was updated to correspond with changes to the Specific Guidance for CRS. - Eligibility criteria were updated for platelet threshold and baseline electrocardiogram. - Duration of infusion of AMG 701 was updated based on current practice of the protocol to correlate with the Investigational Product Instruction Manual. - Hematologic DLT of grade 4 thrombocytopenia was aligned with grade 3 thrombocytopenia DLT criteria. - Restart guidance was clarified for grade 3 or higher events for AMG 701 related AEs and grade 4 unrelated AEs. - Clarified anti-myeloma treatment could commence after end of treatment visit and not after safety follow-up visit. - Clarified immunofixation requirements for both serum and urine. - Serum and urine protein electrophoresis, serum free light chain and immunofixation were to be analyzed at the central laboratory in the dose expansion phase. - clarified requirements on electrocardiograms, deviation windows, medical history collection. - notation of D29 was removed from end of treatment. - Central disease assessment was added in the dose expansion, immune response testing and duplication between absolute neutrophil count and total neutrophils was removed. - clarification regarding In Vitro Diagnostic Medical Device for the minimal residual disease measurement.
04 March 2019	- Cohort extensions of up to 6 additional participants per dose level were to be implemented starting with dose level cohort 9, once the dose level review team judged this and later dose levels were safe. The rationale for these cohort extensions was to more completely assess the safety and activity of dose levels at the higher end of the current escalation scheme, due to the heterogeneity of disease burden and baseline soluble BCMA, which may be a major determinant of safety and efficacy of the investigational product. - Restart guidance for any other AMG 701 related events not meeting DLT criteria that are greater than or equal to grade 3, and any non-AMG 701 related events that are Grade 4 was updated to correct a contradiction in the grade notation between re-start guidance column and interruption/delay column to both be less than or equal to grade 2.
23 August 2019	- Addition of two new cohorts to the dose exploration part of the study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics, and efficacy of AMG 701, if needed to maximally tolerated dose. - Added option allowing the dose level review team to implement an earlier dose step, second dose step, or addition dose during C1. - Updated risk assessment of AMG 701 with focus given to CRS incidence by dose and severity to justify steroid predication tapering. - Added minimum hospitalization requirements for first dose of AMG 701 without glucocorticoid premedication and for subsequent intra-participant dose escalations. - Criteria for permanent discontinuation of AMG 701 were updated. - Minimum expected intervention and restart guidance in cases of grade 2 CRS were updated. - Exclusion criteria updated to clarify prior treatment with any drug or construct targeting BCMA on tumor cells and that participants with a prior history of prostate cancer with a Gleason score < 7 could be included. - Dose expansion part was updated to clarify dosing schedules. - Updated total number of planned participants for the phase 1 dose escalation part of the study to 75.

19 November 2019	- Added Phase 2 expansion. - Removed prior phase 1b expansion group to evaluate AMG 701 activity in participants who had not received an anti-CD38 monoclonal antibody. - Additional clinical data on preliminary efficacy of AMG 701 included. - Inclusion criteria were changed to reflect requirement for at least 3 lines of prior therapy and the requirement for prior CD38-targeted therapy. - Dose modification rules were added for the phase 2 portion. - Recommendations for serial imaging were provided, to permit investigators to monitor extramedullary disease burden and overall disease response per IMWG criteria. - Entry criteria for baseline hematologic function, specifically baseline platelet count for enrollment eligibility, were adjusted to more stringent requirement. - Removed 72 hour requirement for C2 guidance based on CRS in C1 during weeks 3 to 4. - Added AE management guidance for phase 2 portion, including dose reduction and discontinuation parameters for discrete event occurring on treatment. - Modified DLT criteria based on lipase and amylase elevations. - Clarified guidance on infusion reactions and tumor lysis syndrome. - Updated statement of hypothesis added and revisions to statistical analysis plan made to provide sample size justification for the phase 2 portion. - Prior allowance for “dose holidays” in the protocol was removed and was replaced by optional dosing-free intervals for participants achieving complete responses without detectable minimal residual disease using FDA-cleared MRD assay. - Addition of patient interviews for phase 1b portion and patient reported outcome measurement tools to phase 2 portion. - Removal of resburicase as an example of supportive care for tumor lysis syndrome, as based on current experience with AMG 701, the incidence of tumor lysis syndrome does not warrant specific treatment as prophylaxis.
28 January 2020	- Addition of one new cohort to the dose exploration part of the study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of AMG 701, if needed to maximally tolerated dose. - Addition of new extended 1-week eIV cohorts to evaluate the safety, pharmacokinetics, and anti-myeloma activity associated with extended infusions given over either 7 days or 2 days. - Addition of new phase 1b dose-confirmation group to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of AMG 701. - Protocol updated with new information on the target population rationale, with new information on BCMA-targeting bispecific antibody constructs in multiple myeloma. - Key benefits and risk updated with response data from the 20170122 study through 25 November 2019 and safety data through 29 August 2019, with focus to CRS incidence and potential for enhanced risk of infection. - Key secondary endpoints and objectives were updated. - Permitted extension of Cohorts 14 and 15 and to clarify that intra-participant dose escalation may be allowed in cases where participants have experienced Grade 2 CRS. - Updated planned number of participants in each part. - Clarified primary analysis and predicted exposure data, and updated information regarding administration of AMG 701 in the eIV cohorts. - Clarified criteria for restart and restart guidance for grade 2 infusion-related reactions. - Updated guidance for use of tocilizumab in cases of grade 3-4 CRS brief infusions and when AMG 701 given as an extended infusion. - Bone marrow biopsy collection requirements were updated and timing of myeloma disease response assessments were clarified.

20 May 2020	- Added additional treatment arms that include AMG 701 in combination with pomalidomide, with or without, dexamethasone. - Clarified minimum expected intervention for rigors associated with grade 1 CRS in participants enrolled in the monotherapy eIV group. - Updated guidance for restarting treatment with AMG 701 monotherapy in cases of certain grade 3 and grade 4 events. - Updated exclusion criteria to clarify instances when participant with known history of primary plasma cell leukemia may be allowed to enroll. - Streamlined schedules of activities for all study phases to minimized duplicate information.
24 June 2020	- Provided guidance to allow participants (who achieved at least PR) that had an AE of infection, to be able to resume AMG 701 treatment instead of having to permanently discontinue treatment when 2-consecutive doses of AMG 701 were missed.
23 December 2020	- Updated the key safety information for AMG 701 with details for hypophosphatemia as an identified risk following categorization of the safety signal as an Urgent Safety Measure and subsequent to the Dear Investigator letter. - Updated inclusion criteria to require a participant to have serum phosphorus ≥ 2.0 mg/dL (≥ 0.6 mmol/L) within 7 days of study Day 1. - Incorporated monitoring and management of guidelines for hypophosphatemia including providing phosphate replacement therapy and specific AMG 701 infusion withholding and stopping rules.

09 February 2021	- Updated to include CRS mitigation strategies to prevent > grade 1 CRS. - Updated the DLT criteria for phase 1/1b combination study. - Reduced the starting dose of AMG 701 for phase 1/1b combination study. - Removed the investigator attribution of relatedness from the DLT requirement for dose level review team consideration. - Clarified AMG 701 should be discontinued for any grade 4 non-hematologic AEs and all AEs should be considered for dose modification decisions. - Clarified participants may resume AMG 701 for any grade 3 non-hematologic AEs that resolved to less than or equal to grade 1 or baseline. - Clarified to discontinue study treatment if the participant missed more than 2 consecutive doses due to an AE. - Updated to include external members for the Data Review Team. - Updated schedule of activities to include pregnancy test every cycle for females of child-bearing age. - Updated Risk language to align with most recent data cutoff. - Removed Disease Related Events for all parts other than the phase 1 dose exploration monotherapy and added protocol-specific anticipated SAEs. - Added phase 2 objectives and endpoints and updated secondary endpoints. - Consolidated participants in Groups 1 and 2 and updated enrollment numbers. - Updated inclusion criteria to add Gilbert's syndrome as an exception for hepatic function. - Updated time points for biomarker sample collection and clarified participants discontinued from study treatment should discontinue laboratory and biomarker assessments except for safety follow-up and progression bone marrow. - Updated dosing details in justifications and for CRS prophylaxis. - Updated minimal residual disease treatment-free intervals, other protocol required therapies, restart guidance for CRS. - Added pneumonitis jirovecii prophylaxis and efficacy futility analysis.

02 April 2021	- Implemented stopping and dose holding rules for electrolyte abnormalities to further minimize safety risks. - Added hold of AMG 701 dosing for grade 3 non-hematologic AEs and hypophosphatemia AEs. - Added that AMG 701 should be permanently discontinued for any grade 4 electrolyte abnormalities and any Grade 4 non-hematologic toxicity. - Eligibility criteria updated to include related after ≥ 3 lines of prior therapy that must include all approved and available therapies including proteasome inhibitors, immunomodulators, and CD38 directed antibody. - Updated inclusion criteria to include normal electrolyte requirement or if abnormal, but be resolved to grade 1 within 7-days of Day 1. - Added QT assessment requirement and additional electrocardiogram timepoints at C1 and C3 and beyond. - Additional dose exploration cohort added. - Added normal saline 1-hour hydration to be co-administered with AMG 701 during C1.
26 October 2021	- Included the use of siltuximab as an alternative treatment of CRS when tocilizumab was not available.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

This study was discontinued for strategic reasons and not because of safety reasons or lack of efficacy. No participants were enrolled in Phase 1/1b of AMG 701 in combination with pomalidomide with and with without dexamethasone and Phase 2.

Notes: